Gynecological Fistula in the DR Congo

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May 2009
Thesis submitted as part of the Master of Philosophy Degree in International Community Health

Acknowledgement

I would like to express my gratitude for everybody who contributed to this research and for all whom encouraged me to do a Master degree in International Community Health.

First of all, thank you Mathias Onsrud for being a wonderful mentor and friend. You are a big reason for the interest I got in women suffering from fistula and a major contributor to the existence of the Panzi fistula centre. I am grateful for your willingness and patience to advise and assist an economist to understand the complexity of fistula. A special thank you goes to Ellen Onsrud for opening your home and making me feel like a part of the family.

A huge thank you goes to Siri Vangen for valuable advice, enthusiasm and availability during the development of the research protocol, analysis and the write-up of the thesis.

An important thank you goes to Denis Mukwege, Director at Panzi Hospital, for allowing us do the research at Panzi. Your dedication to womens' health in the DRC is exceptional. A special thanks goes to Benge Erasthon, the Panzi Hospital administrator, for always making yourself available and facilitating all the necessary logistics. Your friendship is invaluable!

To someone who made my stay in the DRC like home, thank you Ingeborg Eikeland for all the fun and humor we shared despite the tragic circumstances in the DRC at the time.

My dear friends Inger Anne and Lin, and "middagsgjengen"; Liv Kjersti, Anne og Bjørg Eline for always cheering and giving me the self-belief to finish this work. A special thanks goes to my dear friend and colleague, Jakob Fagerland, for always having confidence in me.

Lien Depp, your valuable help in the statistics were crucial. You are a genius.

I also want to express my gratitude to my employer PYM (Pentecostal Foreign Mission of Norway) for allowing me take time off to get this thesis to the finish line and to the department of International Community Health for their inspiration and dedication to promoting health in developing countries. Thank you to my fellow students for fun, encouragement, challenging discussions and friendships. A particular thank you to my sister Monica and my mother Solfrid who have taught me that nothing is impossible.

Abstract

Background: Gynecological fistula is an international public health problem afflicting many women in the poor countries of Africa and south Asia. Although the magnitude is unknown, it is believed to be a great problem in the DRC. Preliminary hospital data from the DRC indicates that complicated cesarean section and sexual violence are important causes of fistula in addition to obstructed labor. This clinical picture deviates from the results reported from research performed in other Sub-Saharan African countries. There is almost no previous academic research on fistula in the DRC.

Objective: The objective was to establish knowledge of the characteristics of gynecological fistula in the eastern DRC in terms of fistula etiology, patient demographics, fistula attributes and predictors of surgery outcome.

Methodology: A retrospective analysis of hospital records of 604 consecutive patients who received treatment for gynecological fistulas at a fistula referral centre in the eastern DRC during a 24 month period.

Results: 82% of the women developed a fistula following obstructed labor and 17% after medical mismanagement, of which 70% involved cesarean section. 5 cases (0,9%) were caused by sexual violence. The median age at fistula development was 23 and median height 150 cm. 17% of the women were divorced, 41% were primiparous and 34% were parity four or more. The majority spent two or more days in labor in the index delivery and 90% of the babies were stillborn. 42% delivered by cesarean section and 85% of the cesarean sections were performed on dead babies. Women with fistulas from obstructed labor took a median of three years to seek treatment whereas one year for women with iatrogenic fistulas. 31% of the women had previous failed repairs. Overall success rate was 87%, 16% of the women remained incontinent and 13% failed. Failure was significantly associated with previous repairs, amount of fibrosis and fistula size. Incontinence was significantly associated with previous repairs, amount of fibrosis and fistula location. Iatrogenic fistulas had a better outcome, mostly explained by fistula attributes. The success rate for fistula closure for patients with no previous surgeries was 90,7% with 11,5% remaining incontinent.

Conclusion: Obstructed labor was the main cause of fistula. A disturbing high percentage of the fistulas were caused by medical mismanagement, indicating a need for more training and regulation of obstetric services and a call for re-emphasizing the role of midwifes in assisted deliveries. Fistula as a direct result of rape is rare. Age at fistula development was older than most studies which may be indicative of poorly assisted deliveries and lack of access to emergency obstetric care. Treatment delay was also longer than most studies and there is a need to improve fistula awareness and available treatment. Fistulas should be repaired by qualified surgeons only.

Operational terminology

Fistula:	an abnormal connection or passageway between two epithelium-lined organs or vessels that normally do not connect
Gynecological fistula:	fistula involving the female reproductive system (uterus and vagina)
Urogenital fistula:	a fistula pertaining to the urinary and genital apparatus, genitourinary
Obstetric fistula:	a severe medical condition in which a fistula (hole) develops between either the rectum and vagina or between the bladder and vagina after severe or failed childbirth
Vesicovaginal fistula (VVF):	abnormal connection between the bladder and vagina.
Rectovaginal fistula: (RVF):	abnormal connection between the rectum and the vagina.
Iatrogenic fistula:	a fistula caused by medical mismanagement
Obstructed labor fistula:	a fistula caused by obstructed labor
Traumatic Gynecological Fistula (TGF):	a fistula resulting from violent sexual assault

1. Introduction

1.1 Background

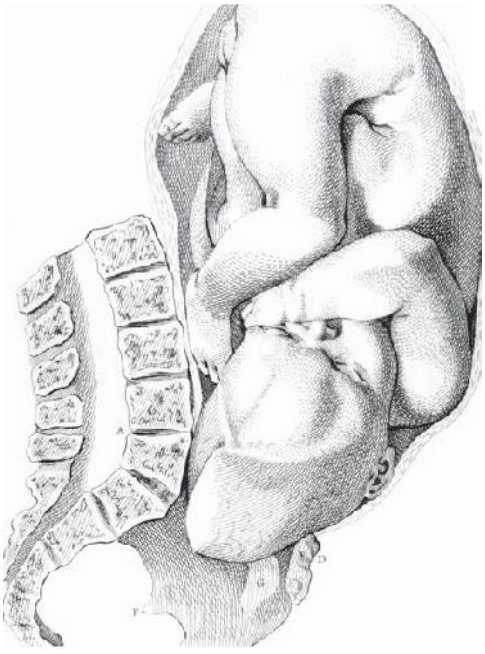
Gynecological fistulas - an international public health problem

Gynecological fistula (fistula) is an international public health problem afflicting many women in the poor countries of Africa and south Asia. Vesicovaginal fistula (VVF) is most common in which there is an abnormal opening between a womans' bladder and vagina. It is a devastating injury resulting in uncontrolled urinary leakage and sometimes feces if the rectum is involved (1). The condition has severe physical consequences, but also social consequences due to stigma attached to the condition. Many women are shunned by their communities and often also by their own families; making them extremely vulnerable and many struggle to survive.

An uncomplicated fistula can in most cases be repaired by a simple surgical procedure. It is normally done by a trained surgeon and essentially involves mending a hole in the bladder or rectum. Sometimes factors such as nerve damage, multiple fistulas, scar tissues, larger fistula or less accessibility to the fistula may require more complex surgical techniques.

As capacity to repair fistulas lags far behind, estimates suggest that as much as 3.5 million women in poor countries have un-repaired VVFs and that 30 000-130 000 new cases develop each year in Africa alone (1). The most common worldwide cause of VVF is obstructed labor (2) which basically mean that "*a woman cannot deliver her baby through her birth canal because of a discrepancy between the size of the fetus and the space available in her pelvis"* (1) (figure 1). There are two main reasons for this cephalo-pelvic disproportion. Firstly, there is a hypothesis of an erect bipedal posture, in which

Figure 1 – Drawing of obstructed labor



18th-century obstetrical drawing of obstructed labor from absolute cephalopelvic disproportion. From William Smellie's *Set of Anatomical Tables*, 1752.

there are limitations in the design of the human pelvis and secondly, the expanding human brain over time (1). Poor contractions resulting in abnormal presentation of the fetal head may also play a role here. The disproportion between the fetus and the available space is the key reason for labor to become obstructed and the woman may be in labor for days. Usually women of low reproductive age, short stature and/or incomplete pelvis growth are predisposed to develop fistula (3). Coupled with poorly assisted home deliveries and no or limited access to emergency obstetric care, complications such as obstructed labor may become devastating, both for the mother and the child. Usually the fetus does not survive the ordeal and the mother sustains devastating injuries.

Fistula related to delivery is often called an obstetric fistula. An obstetric fistula may also be a hole between the rectum and the vagina, called rectovaginal fistula (RVF), though this is not as common as VVFs (4). Some women might have both. A substantial number of fistulas are also caused by surgical trauma, sexual abuse, infections or by harmful traditional practices such as female genital mutilation (FGM) (1).

Obstetric fistula was once the most common type of fistula in the USA and Europe, however with great improvement in obstetric care systems, this condition was eradicated around the mid 20th century. Today this devastating injury is mostly confined to poor developing countries with high maternal mortality. It is widespread opinion that obstetric fistula is a tragic condition, neglected, both by the international community and by the developing countries themselves. The main focus of the current study was to establish knowledge of the characteristics of gynecological fistulas in the DRC and factors influencing the treatment outcome.

Fistula in the DR Congo

VVF is believed to be a great problem in the Democratic Republic of Congo (DRC). The eastern part of the country has been afflicted with many wars and insurgencies, with latest death tolls from the conflict estimated to have reached a shocking 5,4 million (5). Health structures are severely damaged and there is a great lack of emergency obstetric care. Women tend to deliver at home with untrained traditional birth attendants (6). Travel is

difficult due to insecurity affecting access to all types of health services. Maternal mortality ratio is among the highest in the world reaching nearly 1200 deaths per 100 000 births in some places in the eastern part of the country (7).

Panzi Hospital, situated a few kilometers outside the major town of Bukavu in South Kivu, is one of two hospitals in the eastern DRC with expertise in fistula repair. The hospital was established in 1999 with funding from the Swedish Pentecostal Mission (PMU) and was originally planned to give special attention to women with childbirth injuries and to offer obstetric services in order to reduce maternal mortality. Due to the war situation, a large part of the hospital activities have also been devoted to acute medicine.

The Panzi Hospital began to specialize in fistula treatment in the early year 2000 and the hospital repairs hundreds of women with fistula every year. Still there are long lines of women waiting for treatment. Preliminary reports from Panzi and anecdotes from health workers and NGOs suggest that fistulas from rape and sexual assaults may be a great problem. Fistula following cesarean section has also been reported to be frequent. A preliminary analysis of hospital records from Panzi in 2004, showed that nearly 20% of the fistulas were caused by cesarean section and 12% by sexual abuse (8). Similarly, records from 2005 revealed 26% of fistula cases following cesarean section and 2,4% from sexual abuse (9). These causes of fistula are quite uncommon and are not dealt with in reports coming from other countries. Panzi also receives a great number of women with failed fistula surgical attempts performed at

Figure 2 – Map of DRC

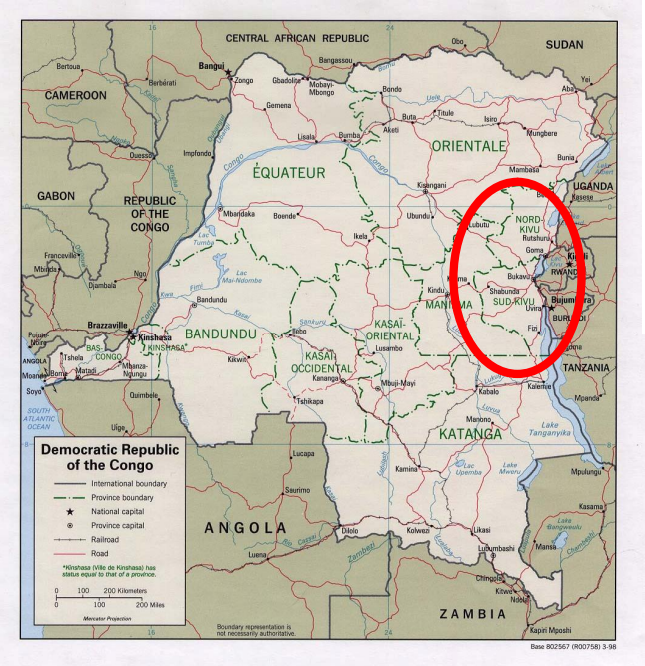


Table 1 - Facts about DRC*

Location	Central Africa
Size	2,3 mill sq.km (< 1/4 size of the USA)
Population	66,5 million (est. 2008)
Religion	Roman Catholic 50%, Protestant 20%, Kimbanguist 10%, Muslim 10%
Maternal MR	1200/100 000 births
Under 5 MR	205/1000
Infant MR	129/1000
HIV/AIDS prev	4,2 %

**From CIA factbook. Mortality ratios from WHO & UNICEF*

other health facilities.

Despite the anticipated magnitude of fistula in the DRC, there is little academic research on fistula in the country. During literature review, only two articles were identified on VVF. One study from 1973 involving 20 cases (10) and one article published in a Norwegian medical journal, which dealt with less than a handful cases (11). It is therefore a need for more knowledge of fistulas as well as a need to shed further light on rape and medical mismanagement as possible causes of this devastating injury.

1.2 Objectives of study

General objective

In order to improve prevention and treatment strategies the main objective of the Panzi study was to establish knowledge of the characteristics of female gynecological fistula in the eastern DRC.

Specific research questions

- How great is the proportion of fistulas actually caused by rape and what are their attributes and healing outcome? This question has been thoroughly dealt with in another report (12), and will only be briefly described in this report.
- What factors are associated with successful fistula repair?
- How do fistulas caused by medical mismanagement (iatrogenic fistula) differ from obstetric fistulas in terms of attributes and healing outcome?
- What are possible public health interventions that may reduce the incidence of obstetric and iatrogenic fistulas, secure quality fistula repair and reduce stigmatization associated with fistula in the DRC?

2. Literature review

2.1 Obstetric fistula

Obstetric fistula has gained international attention in the last 10-15 years. The condition has been researched mostly in developing countries like Nigeria, Ethiopia, Niger and Tanzania. Although the topic is somewhat researched, some claim that the research is inadequate by modern standards of evidence-based medicine, probably because the problem is mainly confined to developing countries (1). Literature is old and most literature and research is anecdotes, case series and personal experiences (1). Unfortunately the condition is not very well known by non-medical people in the west, nor the women themselves, who are at risk in Sub-Saharan Africa. There are no precise estimates on the prevalence of obstetric fistula in poor countries, though it seems to be high in countries where maternal mortality is high (2).

Most studies of obstetric fistula uses observational, analytical study designs, mainly cross sectional studies. The research conducted are typically hospital based, retrospective analysis of case-records/patient records (2;3;13-16). Case control studies are not commonly used. Only three studies were identified using a case control design and that was one study in Nigeria (13) and a recent study in Zambia (17) and in north-eastern Nigeria (18) .

There is a shared view that the main cause of obstetric fistula is prolonged labor and that the major outcome is still-births (2;3;13-16;18). Research uncovers that many women are in labor for several days, often in the presence of a traditional birth attendant and little or no access to emergency obstetric care (1). The majority of research highlights the following predispositions: low reproductive age (2;13;18), biological factors such as short stature and incomplete pelvis growth (2;18), cultural aspects such as female genital mutilation (15) and socioeconomic aspects such as low education and poverty (1). Many studies finds malnutrition to be a risk factor (16), however some claim that this needs to be further researched (3). Many women get divorced or separated from their families (2;3;14;16;18), however, a study in Eastern Nigeria found that the majority of the women were still married, suggesting cultural aspects of divorce practices to play a role (15).

Many studies found that VVFs occurred mostly in first pregnancies (2;14;18), however some studies did not agree with this (13;15;16). Cultural traditions often contribute to exposing the women to fistula. The practice of gishiri cutting (a form of FGM) is reported to be a major cause of fistula in Nigerian women and the cultural practice of marrying at a very low age are often the underlying reason for the high prevalence of fistula in Ethiopia.

The success rate of obstetric fistula repair is in general in the 80 to 90 percentile (2;14), however there is a difference between completely cured and completely closed fistula. A patient who is completely cured is successfully closed and continent (14) whereas a patient with a closed fistula might still suffer from incontinence (2). Success rate is generally lower for completely cured patients, sometimes as low as 60% (2). One main predictor of surgery outcome is identified in some studies to be the amount of vaginal scarring (2;17). This basically means that patients with recurrent fistula have a lower anticipated success rate as these patients tend to have more vaginal scarring due to numerous surgeries. Very few reports have used multivariate analysis to identify predictors of surgical outcome.

The extent of obstetric fistula is unknown in developing countries as most data is based on hospital statistics. There is however, a population based prospective study that was undertaken a few years ago. Nearly 20 000 women in six different west-African cities were followed up until the post partum period (19). Of these, two women developed VVF, estimating the incidence rate to 10.3 per 100 000 deliveries (19). As both of the cases occurred in rural areas, an incidence rate for rural areas was established to be 124 per 100 000 deliveries (95% CI: 15-446), much higher than previous estimates. Incidence rate for major cities was estimated at 0 per 100 000 (95% CI: 0-18). These findings supports previous research that women have a higher chance of developing fistula when living in rural areas as this usually means a long distance to proper obstetric health care. Though the confidence intervals were rather large, it was used to estimate the annual incidence of obstetric fistula in rural Sub-Saharan Africa. Unfortunately the article does not say how these women were selected, nor their composition (urban/rural living, poor, uneducated, height, weight, stunted, parity, age etc), all factors which have been established to be risk factors of fistula development.

2.2 Fistula caused by medical mismanagement

While pelvic tissue necrosis after prolonged labor is considered the main cause of fistulas following obstructed labor, medical mismanagement is considered the major cause of iatrogenic fistulas. The majority of iatrogenic fistulas develop subsequent to cesarean section.

Previous research on fistulas following cesarean sections are mostly single case studies in the developed world. This type of fistula generally follows lower type cesarean section (20;21) often resulting in vesicouterine fistula in which there is an abnormal opening between the posterior wall of the bladder and the anterior wall of the uterus (21). Research claim that over 80 percent of fistulas following cesarean section are vesicouterine fistulas (20-22). Other types of fistulas following cesarean sections are ureterouterine (23), vesicovaginal fistula (24) and ureterovaginal fistula (8). Fistula following cesarean section has been thought to be a rare condition, however a review from 2006 claim that though an infrequent diagnosis, it is not rare (20;22). Fistula following cesarean section seems to be researched most in the western world where modern imaging methods are available (24).

In vesicouterine fistula the bladder may be damaged either by direct injury, inadequate downward mobilization or abnormal sutures. There are recordings of spontaneous healing of fistulas in about 5% of the cases (21;23). Usually vesicouterine fistulas are not approached vaginally due to less accessibility (21), however some argue that vaginal repair should be considered as this is less costly (20;22). Research suggests that previous cesarean sections might be a predisposing factor (23), however this needs to be studied further. A retrospective study of 12 patients with vesicouterine fistula over a period of 10 years showed that more than 50% of the cases resulted from an emergency caesarean section, with nearly 60% presenting after their second cesarean section (20). This indicates that emergency situations and/or more than one cesarean section may be risk factors. Lower segment cesarean sections are thought to be an isolated risk factor for the development of vesicouterine fistula (23). Another study claim that the recurrence of fistula are higher in patients with a history of prolonged labor. This is due to the damage of tissues (pressure necrosis) compared to the clean cut injury in cesarean sections (24).

There are no other reports in which the incidence of fistula following cesarean section is as high as preliminary records from the Panzi Hospital. Most previous studies are case studies in the developed world with no comparison with fistulas caused by obstructed labor. Most studies with several cases have been undertaken over many years, starting in the 80s. Changes in the fistula diagnose over time could be a source of information bias in research collection during a time period up to 25 years.

2.3 Traumatic gynecological fistula

Until recently little focus has been placed on traumatic gynecological fistula (TGF), an injury that may arise from violent sexual assault. The first ever conference on TGF was held in Addis Ababa in September 2005 (25). In the anticipation of the meeting, a literature review called the ACQUIRE project was conducted to uncover current knowledge about the condition (26). The ACQUIRE project found that the DRC probably had the largest number of women suffering from TGF, however that documentation was limited (26). A recent article on fistula related to sexual violence was published in May 2008 (27). The report described seven cases of fistula caused by sexual violence in the DRC. The description of cases focused on the course of event, rather than a medical description of the fistula itself. Thus, it was not convincing that the etiology assigned to the fistulas were correct. The article found that several fistulas assumed to be caused by sexual violence actually was either indirectly or not caused by sexual assaults.

Assessing the magnitude of TGF is challenging due to the limited number of cases and/or the stigma and shame associated with rape. The physical repair of TGF is similar to obstetric fistula, however a TGF does not require the pre-operative wound healing period as with obstetric fistula, since there generally has been less pressure on the tissues (26). On the contrary, although fistulas of any kind require psychosocial healing due to stigma and shame, the management of the psychological needs of a woman suffering from TGF may require more time and professional trauma counseling (25).

Since there are almost no academic studies on fistula in the DRC, the current study bridges a gap of knowledge on fistulas in the country. This is true for obstetric fistulas, but not the least for fistulas following medical mismanagement and TGF. Fistulas due to faulty cesarean sections have rarely been studied with numerous cases over a short time period and there is

a great lack of documentation and research on fistulas following rape. TGF is believed to be common following sexual assaults, however there are some indication that these numbers might be overstated. The DRC and the Panzi Hospital was therefore considered a well suited place for examining this issue. Thousands of brutal rapes have been committed in the eastern DRC over the last 10 years. Panzi Hospital have received and treated a great portion of these patients.

3. Methodology

3.1 Study design

The study was a retrospective cross sectional analysis of patients receiving treatment for gynecological fistulas at the Panzi Hospital in Bukavu, DRC, during a 24 month period.

3.2 Study population

The study population was patients treated for gynecological fistula with curative intent at Panzi Hospital in the period between November 1, 2005 and November 30, 2007. All together 671 gynecological fistula operations performed on 604 patients were investigated.

According to the operating theater protocol, the number of fistula and incontinence operations during the above mentioned period was 795. Our study included 707 (89%) of these, however excluding surgeries relating to incontinence, the total number of fistula operations investigated were 671. The Panzi Hospital is a referral hospital for fistula treatment in the eastern DRC and receives patients from the entire region. Patients were mostly from the eastern parts of the DRC, though many also came from the neighboring countries Rwanda and Burundi.

3.3 Measurements and instruments

Information about the patients was obtained from a standardized registration form designed for a project financed by the Swedish Pentecostal Mission (PMU), patient cards and patient surgery forms recorded by Panzi health personnel at admission and during hospitalization.

3.3.1 Registration form (annex 1)

The registration form included questions asked to the patient and medical assessment made by the consulting doctor / surgeon.

3.3.1.1 Demographics and obstetric history

This part of the form was filled out during the first medical consultation, in general by the consulting doctor or the assigned surgeon. It included information such as patients' age when presenting at the hospital, age at marriage, age at first birth, height, weight, geographical origin, marital status, obstetric history such as obstetric formula (number of pregnancies, births, abortions, live children and dead children), cause of the fistula, duration of fistula, number of previous repairs and place of previous repair. Except for marital status all of these questions were open ended questions. The questionnaire also included questions with regards to the delivery causing the fistula (index delivery) with questions such as duration of labor, place of delivery, mode of delivery, delivery complications and status of fetus. The latter questions were all closed-ended.

3.3.1.2 Surgical information

This part of the form was filled out by the surgeon performing the fistula surgery. It included information such as name of surgeon, type of anesthetic, route of repair, type of repair, number of fistulas, type of fistula, place of fistula, length of fistula, size of fistula, amount of fibrosis, bladder capacity, status of cervix and urethra, information on RVF (if applicable), duration of surgery, prognosis and whether the patient had other associated surgeries. Except for the name of the surgeon, all these questions were closed ended. We coded the performing fistula surgeon into three categories; junior-, senior- and guest surgeon. The doctors in the Panzi training program were classified as juniors, the two experienced fistula surgeons, Dr. Mukwege and Dr Nessy were classified as seniors and all visiting doctors such as Dr. Kelly, Dr. Fiona, Dr. Onsrud and the team from Addis were coded as guest surgeons.

3.3.1.3 Postoperative information

This part of the form was also filled out by the surgeon performing the fistula surgery. It included information such as treatment given, post operative complications, whether the fistula was successfully closed, whether the patient suffered from incontinence upon leaving the hospital and length of stay at Panzi. When it comes to successful outcome of fistula repair, this study used two classifications; successful closure or completely cured. Similarly to common definitions by fistula surgeons, successful closure has been defined as "*the*

fistulous opening itself has been completely closed and that there is no leakage of urine at the site of the repair", however due to various reasons such as small volume bladder or damaged sphincter function, the patient may still be suffering from incontinence (2). Completely cured was defined as complete closure of the fistula and no incontinence while out of bed. Urodynamic testing was not available. In some cases a dye test was performed. The outcome of surgery was determined at the time of hospital discharge. Long-term effects were not measured and beyond the scope of this study.

The patient registration forms were handed to us upon arrival at Panzi hospital. In the majority of cases, the surgical information section and the post-op section were thoroughly filled out by the surgeon. We did however find that some information was missing, especially with regards to the patients' demographics and obstetric information. We therefore requested to have all the additional patient records such as patient cards and patient surgery records in order to obtain additional information. This was quite a puzzle, however with perseverance and patience we managed to retrieve most of the patient records and obtain much of the missing information. In some cases we failed to obtain information and had to record missing variables. See below for a description on how we handled missing information/variables.

3.3.2 Variables in patient cards and surgery records

Upon arrival and first point of interaction with Panzi Hospital staff, each fistula patient got a patient card when examined by a nurse. For the most part, information such as height, marital status, obstetric formula and patient history such as course of events related to birth, rape or maltreatment were recorded in these cards, also a drawing of the fistula. We are of the understanding that the patient cards were supposed to follow the patient when leaving the hospital to be used for her own records or when meeting the health system again. However for some reason these cards remained at Panzi Hospital.

The patient surgery records contained information such as course of events and details about surgery procedures. It was up to the surgeon to decide what information to include in the surgery records. Some forms had much information and some had scarce information.

The information in these two records (patient card and surgery record) assisted us in finding information that were missing in the questionnaire as well as sufficient information needed in order to establish the correct fistula etiology.

3.3.3 Determining fistula etiology

One of the objectives of the study was to determine the characteristics of gynecological fistula in the DR Congo, with special attention to those of iatrogenic causes and those caused by sexual violence. While pelvic tissue necrosis after prolonged labor is considered the main cause of obstructed labor fistula, medical mismanagement is considered the major factor for the development of iatrogenic fistula. The examining surgeon's decision to attribute a fistula occurring after a caesarean section into the iatrogenic group or to the obstructed labor group was influenced by the history and the clinical picture. In a few cases, the etiology was not recorded and the allocation was done by us. To determine the various influencing factors, we analyzed history, clinical characteristics and fetal outcome from all records of fistula patients who had undergone a caesarean section prior to fistula development, keeping in mind that ischemic damage after prolonged obstructive labour could lead to a fistula whether the woman was delivered by caesarean section or not. The iatrogenic fistulas were then categorized into two main categories, those related to obstetric malpractice (cesarean section, cesarean hysterectomy, vacuum, symphysiotomy and various obstetric manipulations) and those related to gynecological malpractice (hysterectomy and gynecological manipulations).

We did a similar categorization for those fistulas claimed to be caused by sexual violence, dealt with in a separate report (12).

3.4 The use of co-researchers and assistant

The main supervisor, Dr. Mathias Onsrud, MD Gynecologist & PhD, took part in the field work as an advisor. He was consulted on technical medical issues as well as analyzing patient / surgery information that were ambiguous. He was also the main expert to determine the true fistula etiology when this was not clear in the patient records. The co-supervisor Dr. Siri Vangen is a gynecologist with experience from research in epidemiology and international

maternal health. She advised in developing the study protocol, analyzing the data and writing the thesis.

Dr. Roger Luhiriri, junior fistula surgeon, assisted in finding the missing information in the questionnaires and was also used as an advisor on technical medical issues. The Medical Director at Panzi, Dr. Mukwege, advised throughout the research and was consulted when interpreting the results and findings. Dr. Mukwege is a gynecologist with extensive experience in fistula repair.

3.5 Data input

All the patient files (questionnaires) were gathered and each registration form was assigned a case number. A code book for each variable was prepared beforehand. The data was recorded into Excel and later converted into SPSS version 16. To ensure quality of data entry, random cross checks of the data entered electronically from the patient files were done. Data collection and data input took about 7 weeks. Data input was done by Sjøveian, the author of this report.

3.6 Data processing and analysis

All analysis were done using SPSS, using a significant level of $p<0.05$.

Cleaning of data The first step of was to clean data. Each variable was cleaned by doing descriptive analysis of the data in order to detect variables that could be invalid or wrongfully entered into the system.

Descriptive analysis Descriptive analysis was carried out using frequencies (n) and percentages (%) for all categorical data. For continuous variables, measures of central tendency such as means and standard deviations were performed. For variables not normally distributed, median and range were used. Continuous variables and variables with more than three categories were grouped into two or three categories and were analyzed in cross tabulations. When investigating the different characteristics of etiology groups (iatrogenic and obstructed labor) cross tabulations and chi-square test for significant differences were used. Fishers' exact test was used when variable /cells had less than 5 counts. For analysis of treatment outcome, variables were analyzed for their potential

impact on surgery outcome using cross tables. Chi-square or Fishers' exact test was used to measure significant differences within the table, and variables with significant influence on the surgery outcome were included in regression analysis.

Univariate logistic regression Factors believed to impact successful fistula closure or continence was analyzed using univariate regression analysis.

Multivariate regression Based on the bivariate analysis (cross tabulations) and significant factors in the univariate regression as well as consideration of previous research findings and clinical experience, we entered selected variables into a multiple regression model to determine variables significantly influencing the outcome of surgery. Variables intended to be used in the multivariate analysis, were checked for correlation. Variables with a correlation of ± 0,6 were considered strongly correlated. None of the variables where strongly correlated.

3.7 Missing data

Some information was missing in the patient files at Panzi. Information on height was missing in as much as 318 of 604 women (53%). Other variables identified with more than 10% missing were marital status 107/604 (18%), parity 74/604 (12%), duration of labor 170/604 (28%), place of delivery 69/604 (11%), and location of fistula (12%). We do not have any indication that these were systematic omissions. In all descriptive analyses, missing data were omitted from the analysis and only valid percentages were used. Missing data were also omitted in the regression analysis. Of those variables investigated in the regression analysis, the amount of missing variables was few and did not influence the results. An overview of missing variables in the regression analysis is outlined in table 2.

Table 2 – Missing variables in the regression analysis

Variables	n	%
Total operations=671		
Closure of fistula	6	0.9
Fibrosis	24	3,6
Number of previous repairs	21	3,1
Distance to fistula	65	9,7
Dimension of fistula	63	9,4
Location of fistula	82	12,2
Duration of fistula	58	8,6
Total patients=604		
Age at repair	52	8,6

3.8 Ethical considerations

Ethical clearance was obtained from the regional committee for medical research ethics (REK) in Norway and was notified to the Norwegian Social Science Data Services (NSD). We also obtained clearance from the director at Panzi Hospital and from PMU Interlife, the main donor to the Panzi Hospital. There is no official medical research ethics committee in the DRC.

The study did not raise major ethical questions. The investigation was based on already existing data in medical records concerning previously treated patients and was sort of a product control meant mainly for internal use. All data was registered anonymously, not identifiable. Each patient was assigned an ID number and only this ID followed throughout data handling. The list linking patient identity with ID number was kept separately during the study and was destroyed after the data was quality assured. The patient records used during the field study was kept in a locked room in which keys were kept by Sjøveian and Dr. Onsrud.

We did not collect consent for access to data in medical records. This was considered too complicated in the current context to carry out and could also raise further ethical concerns. The patients usually travelled long distances and had no addresses listed in their hospital record. Besides, the postal services in the DRC are non-functional and alternative ways of getting in contact with the women was impossible. Most of the women in this study were illiterate. Using other informants in order to obtain contact would have raised additional ethical questions. Otherwise it would have been of great interest to have obtained information on the long-term effect of women treated for fistula. This question was outside the scope of this study. The value of the study was considered to offset the disadvantage of deviating from the key principle of obtaining consent for the use of data in medical records (personal sensitive information) for research.

Neither the project leader nor student was ever in contact with the patients included in the study and were assigned roles as researchers only. The locally recruited MD had very little if any contact with the patients studied. The study did not have any influence on further treatment of the patients. See annex 2 for ethical clearance letter from REK Norway.

4. Result

4.1 Descriptive results

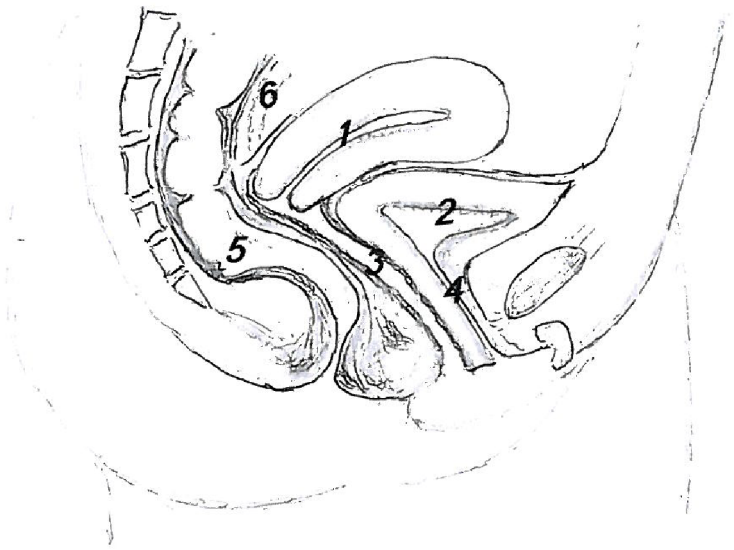
Table 3 – Main fistula type and etiology

	Urogenital		Rectovaginal		Combination		Total	
Etiology	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Obstructed labor	447	77,6	6	1,0	17	3,0	**470**	**81,6**
Iatrogenic	95	16,5	1	0,2	1	0,1	**97**	**16,8**
Sexual trauma	3	0,5	2	0,4	0	0,0	**5**	**0,9**
Other	1	0,2	3	0,5	0	0,0	**4**	**0,7**
Total	546	94,8	12	2,1	18	3,1	**576**	**100,0**
Not determined							28	

During the period of study 671 fistula operations were performed on 604 women. Fistula etiology was determined in 576 women (table 3). The majority of women (95%) suffered from urogenital fistula. 12 women (2%) had rectovaginal fistula only, whereas 18 patients (3%) had both urogenital and rectovaginal fistula. Fistulas involving rectum were normally operated in two or more steps and with a temporary colostomy. Characteristic and treatment results of patients with rectovaginal fistulas only, will not be given here.

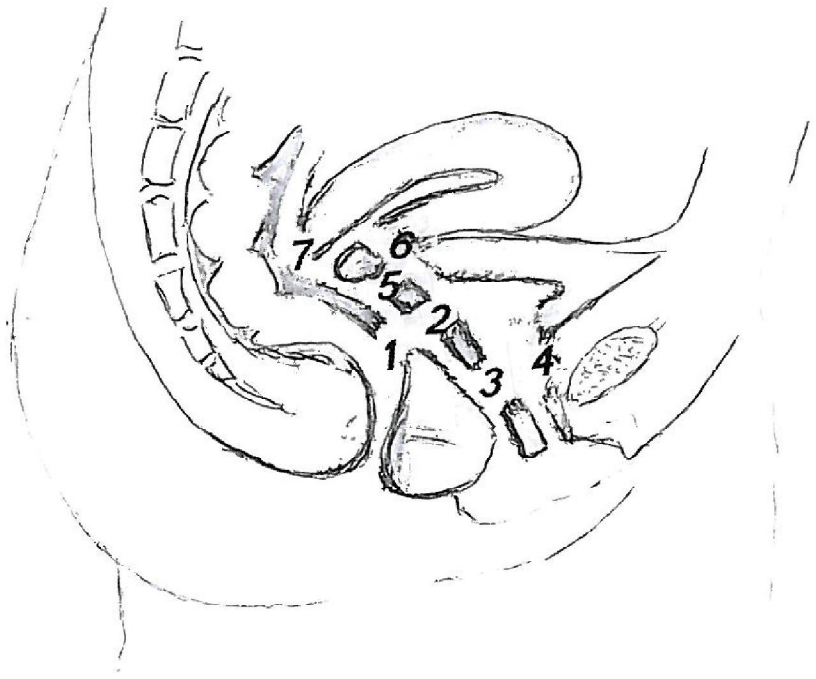
Among the urogenital fistulas, 380 (67%) were vesicovaginal fistulas (VVF), 81 (14%) were vesicourethrovaginal, 22 (4%) were urethrovaginal, 33 (6%) were vesicouterine and 32 (6%) were ureterovaginal fistula. Figure 3 illustrates the normal anatomy of a woman while figure 4 illustrates the various fistula types.

Figure 3 – Normal anatomy



1 uterus, 2 vesica (bladder), 3 vagina, 4 urethra, 5 rectum and 6 ureter

Figure 4 – Fistula types



1 rectovaginal, 2 vesicovaginal, 3 vesicourethrovaginal, 4 circumferential, 5 juxtacervical, 6 vesicouterine and 7 ureterovaginal

470 of the fistulas (81,6%) were associated with obstructed labor, 97 (16,8%) were due to iatrogenic causes and 5 (0,9%) were considered to be traumatic gynecological fistula (TGF). Four fistulas (0,8%) had other causes, three of which were spontaneously appearing rectovaginal fistulas not related to delivery.

4.1.1 Patient characteristics

Table 4 - Patient characteristics and obstetric information

	Obstructed labor		Iatrogenic		
Characteristics	**n**	**%**	**n**	**%**	**p-value**
Age at fistula development					
<20 yrs	153	34,2	10	10,5	
20-34	246	55,0	58	61,1	
>34 yrs	48	10,7	27	28,4	<0,001
Not given	23		2		
Parity					
One birth	205	46,0	15	16,3	
Two births	76	17,0	12	13	
Three births	41	9,2	10	10,9	
Four or more births	124	27,8	55	59,8	<0,001
Not given or n/a	24		5		
Outcome (index delivery)					
alive	32	7,1	14	17,3	
still born	416	91,8	64	79,0	
dead before 48 hrs	5	1,1	2	2,5	
twins - one alive	0	0,0	1	1,2	0,001*
Not given or n/a	17		16		
Mode of delivery (index delivery)					
Vaginal	212	46,5	13	15,3	
Cesarean	157	34,4	69	81,2	
Symphysiotomy	2	0,4	2	2,4	
Vaginal+vacum	85	18,6	1	1,2	<0,001*
Not given	14		12		
Place of delivery (index delivery)					
Home	113	25,7	4	4,9	
Health facility	303	69,0	75	92,6	
Forrest	23	5,2	2	2,5	
Not given or n/a	31		16		<0,001*
Marital Status					
Single	21	5,2	5	6,0	
Married	244	60,8	62	73,8	
Divorced, separated, abandoned	76	19,0	9	10,7	
Widow	60	15,0	8	9,5	0,108
Not given	69		13		

Obstructed labor n=470 women, Iatrogenic n=97 women * Fisher's Exact Test

Age The median age at fistula development was 23 (range 3-60). The majority of the patients (55%) were between 20 and 34 years old, while 31% were below 20 years old and 14% were over 34 years. The patients had suffered from fistula for a median of two years before seeking treatment (range 0-45 years). As many as 195 women (35%) had untreated fistula for more than five years. There were differences in the age composition between fistulas caused by obstructed labor and those of iatrogenic origin. For the fistulas caused by obstructed labor, the median age at fistula development was 22 (range 11-51) while in the iatrogenic group the median age was 28 (range 15-49, p<0,001). 34% of the patients in the obstructed labor group were below 20 years of age at the development of fistula, whereas only 11% in the iatrogenic group were below this age. In the obstructed labor group, 11% (48 patients) were above 34 years old, as compared to 28% for the iatrogenic group.

Parity Of the patients studied, 216 (41%) had given birth once and 178 (34%) had four or more births. Of the women with one birth only, nearly 92% got a fistula due to obstructed labor. There were differences in parity in the two groups. In the obstructed labor group, 46% of the patients had only one birth while 28% had four or more births. In the iatrogenic group, the corresponding numbers were 16% and 60%.

Height The median height for the group was 150 cm (range 131-176). However, in as many as 318 patient records, information about height was missing. There was very little difference in height between the obstructed labor group and the iatrogenic group, with median heights of 150 cm (range 131-176) and 149 cm (range 135-164), respectively.

Marital Status As for social consequences of fistula, 17% women were divorced, abandoned or separated at the time of treatment, 312 (63%) women were married, 14% were widows and 7% were single. It appeared that the duration of fistula impacted marital status. For patients that had suffered from fistula for less than five years, 14% were abandoned, divorced or separated. For those that had suffered between five and 10 years as many as 23% were abandoned, divorced or separated (p<0,001). It appeared to be differences between the two etiology groups. While 11% of patients in the iatrogenic group were either divorced, separated or abandoned, this was the case for 19% of the patients in the obstructed labor group.

Treatment delay The delay before fistula repair was longer in the obstructed labor group (median of 3 years, range 0,06-45) than in the iatrogenic group (median 1 year, range 0,04-30) ($p<0,001$ Mann-Whitney test). For comparison, the median delay for the fistulas caused by sexual violence (5 patients) were a little less than 4 months (range 0-0,83 years) (12).

Previous repairs 179 patients (31%) had undergone previous repairs at other health facilities before treated at Panzi hospital. The majority of these (58%) had one previous attempt, while 23% had two previous attempts. The remaining 19% had three or more previous attempts. 143 patients (31%) in the obstructed labor group had undergone previous repairs either at Panzi or other health facilities. Of the iatrogenic fistula patients, 22% (20) had undergone previous repairs.

Origin The majority of the patients (57%) came from the home province South Kivu, 22% from Burundi, 17% from North Kivu and a small number came from other DRC provinces (3%) and Rwanda (1%). 24 patients treated did not indicate province in their patient records. The patients from North Kivu tended to be younger than those from the other areas. 49% of women from North Kivu were below 20 years old at the onset of fistula, whereas from South Kivu only 29% of the patients were below 20 years and Burundi only 23% were below 20 years ($p<0,001$, Chi-square test). 18% of the patients from South Kivu were older than 34 years old, however only 5 (5%) of the North Kivu patients, 24% of patients from other DRC provinces and 13% of patients from Burundi were over 34 years of age. Similarly, 60% of the North Kivu patients had given birth only once, while for the patients from South Kivu and Burundi, this was 34% and 50% respectively. The patients from South Kivu tended to be shorter than those from other provinces. Of the South Kivu patients, nearly 68% were below 150 cm. Among patients from North Kivu, other DRC provinces (Rwanda is grouped here) and Burundi, 51%, 31% and 47% were below 150 cm respectively ($p=0,002$).

Patients from North Kivu and other DRC provinces, 45% and 44% respectively, had a higher percentage of patients with previous repairs before coming to Panzi. Only 29% of the South Kivu patients had previous repairs, while 23% of the Burundi patients had prior attempts to repair their fistula ($p= 0,002$).

South Kivu had more iatrogenic fistula patients and North Kivu and Burundi relatively more patients with obstructed labor fistula. 19% of the South Kivu fistula patients had iatrogenic causes, compared to 12% for North Kivu patients and 12% for Burundi patients (p=0,075 Fishers' Exact test).

4.1.2. Obstetric information

Obstetric history Median number of pregnancies were 2 (range 0-15). Median number of births were also 2 (range 0-13) and median number of children alive were 0 (0-10). 57% of the women that had given birth had no living children at present.

Outcome of delivery related to fistula development For the index delivery, 482 babies (90%) were still born, 48 babies were alive (9%) and 7 were dead before 48 hours. In 55 patients the outcome for the child was not recorded and in 11 cases the fistula development was not related to child birth. For the babies born alive (48 babies), about 60% had been delivered by caesarean section, 21% were delivered vaginally and 17% delivered by vacuum.
The outcome for the baby was better in the iatrogenic group. 17% (14 babies) were born alive, while only 7% (32 babies) were born alive in the obstructed labor group (p<0,001 Fisher's Exact test). In 33 patients, the outcome for the child was not recorded. The overall reproductive outcome was also better for the women in the iatrogenic group. Of 457 births, 252 children (55%) were alive while in the obstructed labor group, out of 1282 births, 486 (38%) were alive.

Duration and mode of labor Nearly 60% of the women had been at least 2 days in labor. There was no difference in the number of days in labor between the two etiology groups. For fistulas related to delivery (obstructed labor group plus iatrogenic fistulas related to obstetric malpractice), 226 women (42%) delivered vaginally, 86 patients (16%) delivered by vacuum, 228 (42%) delivered by caesarean section and in four patients a symphysiotomy was performed. As much as 85% of the babies born after caesarean section were still born, whereas 95% of babies born vaginally were still born.

There were differences in the mode of delivery in the two groups. The vast majority (81%) of the iatrogenic group delivered by cesarean section, while in the obstructed labor group, 34% delivered by cesarean section. 297 women (65%) in the obstructed labor group delivered vaginally, of these 85 (19%) with vacuum. Only 14 women (17%) in the iatrogenic group delivered vaginally, of which only 1 with vacuum (p< 0,001 Fisher's Exact test).

Place of delivery 380 women (73%) gave birth in a health facility, 117 (22%) at home and 26 (5%) in the forest. There were no major differences between place of birth according to number of previous deliveries. 24% of the primipara women (50 persons) gave birth at home, while 21% of those with four or more births (34 persons) gave birth at home (p= 0,76 Chi-square test). There were significant differences according to etiology groups: 92% of the women with iatrogenic fistulas delivered at a health facility, while 69% of the obstructed labor group did the same. Only 5% of the iatrogenic group delivered at home, while nearly 26% of the obstructed labor group delivered at home (p< 0,001 Fishers' Exact test).

Duration in post-operative stay and cost The median length of stay after surgery was 17 days (range 7-150 days). The stay in the postoperative ward was similar for the two groups. The mean cost (paid by the donor) was USD 198 per treatment (range USD 110-1064).

4.1.3 Characteristics of iatrogenic fistulas vs. fistulas caused by obstructed labor

In 97 women, an iatrogenic cause was considered most probable. In 11 of these patients the cause was gynecological malpractice. The others were related to obstetrical malpractice.

Gynecological manipulations Three women were raped in the 4th, 5th, and 6th months of pregnancy. This provoked an abortion, and manual extraction of placenta and/or curettage was performed. One of these women later developed vesicovaginal fistula and two developed vesicourethrovaginal fistulas. The sites of these fistulas, all being outside the uterus, highly suggest that the intervention had been wrongly performed.

Gynecological operations Two vesicovaginal fistulas and one ureterovaginal fistula developed after vaginal hysterectomy. The operations were performed for genital prolapse.

8 fistulas, 4 vesicovaginal and 4 ureterovaginal, occurred after abdominal hysterectomies. These operations were performed for benign uterine tumors.

Obstetrical interventions Table 5 shows various types of obstetrical interventions considered to have provoked the various types of fistula.

Table 5 - Iatrogenic fistulas occurring following obstetric intervention

	Vesico-urethro vaginal	Vesico-vaginal	Vesico-uterine	Uretero vaginal	Other	Total n	Total %
Cesarean section							
- 1st Cesarean section		12	15	10		**37**	**41,6**
- Repeated cesarean section		7	9	6		**22**	**24,7**
- Cesarean + hysterectomy*		4	1	4		**9**	**10,1**
Vacuum + cesarean			2	3		**5**	**5,6**
Symphysiotomy	4					**4**	**4,5**
Obstetrical manipulations	1	7	2		2	**12**	**13,5**
Total	5	30	29	23	2	**89**	**100,0**

** for ruptured uterus*

Cesarean section In 37 women with first-time cesarean and 22 women with repeated cesarean section, mal-performed surgery was considered the main cause of fistula. This means that 10% of the total fistula material (59/576) was caused by caesarean section. In 40 of these cases (67%), the type of fistula was either vesicouterine or ureterovaginal.

Cesarean hysterectomy The 9 hysterectomies performed at the time of the cesarean were all done because of uterine rupture. Obstructed labor was probably the cause of the rupture, although inappropriate technique for hysterectomy is considered the main cause of the fistula.

Vacuum+cesarean In 5 women, unsuccessful attempts of vacuum extraction were followed by cesarean section. Two women got vesicouterine fistulas and three got ureterovaginal fistulas. Wrongly applied vacuum, faulty cesarean technique and preexistent tissue ischemia might have acted together and created a fistula.

Symphysiotomy Four women developed fistula after symphysiotomy performed to relieve obstructed labor. A complete destruction of the urethra and tissues around urethra was

found. Details of these cases have been described in an earlier publication (28) and will not be repeated here.

Obstetrical manipulations The 12 cases of obstetrical manipulations were all attempts of manual extraction of placenta and/or curettage, performed at remote health centers by most likely uneducated personnel. Both vesicovaginal and vesicouterine fistulas developed. One woman, who delivered in the forest, was cut by a razor blade and developed a vesicovaginal and a rectovaginal fistula.

Table 6 highlights the major differences and similarities in the characteristics of the fistula by etiology group and figure 5 summarizes type of fistula by etiology.

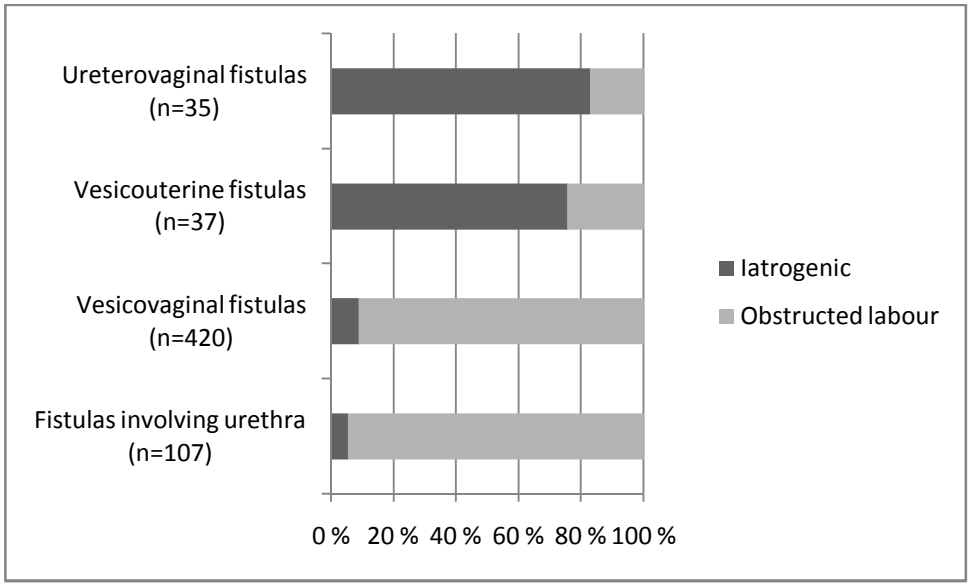
Table 6 - Fistula characteristics and etiology

	Obstructed labor		Iatrogenic		
	n	%	n	%	p-value
Number of previous repairs					
None	319	69,1	70	77,8	
One	82	17,8	14	15,6	
More than one	61	13,2	6	6,7	0,159
Not given	8		7		
Place of fistula					
VUF, jxtcerv, VVF	250	57,9	57	85,1	
Jxturet, urethral	136	31,5	8	11,9	
Circumferential	46	10,7	2	3,0	
Not given or n/a	38		30		<0,001*
Size of fistula					
<=2 cm	297	65,7	46	75,4	
3-4 cm	115	25,4	12	19,7	
>4 cm	40	8,9	3	4,9	0,291
Not given	18		36		
Amount of fibrosis					
Without fibrosis	179	39,4	49	53,3	
Slight to moderate fibrosis	208	45,8	38	41,3	
Severe to vaginal stenosis	67	14,8	5	5,4	0,012
Not given	16		5		
Outcome of surgery (closure)					
Successfully closed fistula	413	88,8	87	89,7	
Failure to close fistula	52	11,2	10	10,3	0,484
Not determined	5				

Obstructed labor n=470 women, Iatrogenic n=97 wom * < 5 counts.
VUF= Vesicouterine Jxtcerv=juxtacervical Jxturet=juxtaurethral

Localization of the fistula For the urogential fistulas 60% were either vesicovaginal or vesicouterine. In the obstructed labor group, the most common sites were vesicovaginal (71%) and vesico-urethrovaginal (16%), while in the iatrogenic group the main localizations were vesicovaginal (35%), vesicouterine (28%) and ureterovaginal (25%).

Figure 5 – Fistula type and etiology



Thus, the fistulas in the obstructed labor group, tended to be placed low: 25% juxtaurethral, 31% in the middle of vagina and 26% juxtacervical. The iatrogenic fistulas tended to appear higher up: 38% vesicouterine, 34% juxtacervical and 12% in the middle of vagina (12%). The difference is significant with a p-value < 0,001 (Fisher's Exact test).

Size Fistulas in the obstructed labor group tended to be larger in size than the fistulas in the iatrogenic group, however the difference was not significant. 66% of the obstructed labor fistulas were less than or equal to 2 cm in size, while 9% were more than 4 cm. For the iatrogenic group, 75% were less than or equal to 2 cm in size and 5% more than 4 cm.

Amount of fibrosis The fistulas caused by obstructed labor had more fibrosis than those of iatrogenic origin. In the obstructed labor group, 39% were without fibrosis, 46% had slight to moderate fibrosis and 15% had severe fibrosis or vaginal stenosis. In the iatrogenic group,

53% were without fibrosis, 41% had slight to moderate fibrosis and 5% had severe fibrosis or vaginal stenosis (p=0,012). All five fistulas caused by sexual trauma were without fibrosis.

4.1.4 Traumatic Gynecological Fistulas

Due to the international attention to fistula related to sexual violence in the DRC, the author and main supervisor reviewed those cases and published the findings in International Journal of Gynecology and Obstetrics in December 2008 (12).

Preliminary hospital records from Panzi, the Acquire project (25;26), anecdotes from hospital workers and media coverage have indicated sexual violence to be a major cause of fistulas in the DRC. One of the major aims of the study was therefore to determine the true magnitude of traumatic gynecological fistulas caused by sexual violence. Of the 604 women operated, 24 (4%) reported that their fistulas had been caused by sexual violence. By thoroughly examining the patients' medical records and patient cards, it was determined that only five of these (0.8%) had developed fistulas as a direct result of forced penetration with foreign objects and/or gang rapes. A summary of these findings is presented in table 7.

Table 7 – Fistulas directly related to sexual violence (n=5)

Patient	Age, yrs	Parity	Children alive	Type of violence	Fistula type/location	Size, cm	Scar tissue	Treatment delay, months	Treatment result
1	3	0	0	TPFO & Rape	RVF Perineal tear	ND	No	1	Success
2	13	0	0	TPFO	UVF	2	No	3	Success after 3 operations
3	14	0	0	Gang rape (5 men)	VVF, Mid-vaginal	1	No	10	Success
4	19	0	0	Gang rape	RVF Perineal tear	1	No	3	Success
5	37	7	4	Gang rape 3 weeks after cesarean	VVF, Mid-vaginal	1	No	8	Success

TPFO=traumatic penetration with foreign objects; RVF=rectovaginal fistula; UVF=urethrovaginal fistula; VVF=vesicovaginal fistula; ND= not determined.

Of the remaining patients, 6 had a fistula before they were raped, 9 developed iatrogenic fistulas following inappropriate instrumentation to manage rape-induced spontaneous abortion or stillbirth or after abdominal hysterectomy, and 4 developed fistulas after

prolonged and obstructed labor (12). These patients were therefore classified into the iatrogenic or obstructed labor group. The conclusion of the case study was that traumatic gynecological fistulas are rare compared to obstetric fistulas, even in conflict zones. Fistulas indirectly related to sexual violence are likely to be more common than those directly related (12).

4.2 Surgical outcome

Surgical outcome is reported in terms of the proportion of operations, not patients. Of all operations, 87% (579/665) were successfully closed. 104 (16%) of these patients remained incontinent and 475 women (71%) were considered completely cured. The success rate for fistula closure were similar for the fistulas caused by obstructed labor and those caused by medical mismanagement, with success rates of 89% and 90% respectively. Postoperative urinary incontinence was however more frequent in the obstructed labor group than in the iatrogenic group, 18% vs. 6% (p=0,05). Factors influencing outcome of surgery are presented in table 8. Regression analysis is shown in next section.

Table 8 – Cross tabulation fistula characteristics and outcome of surgery

Fistula attributes	Cured		Incontinence		Failed		p-value
	n	%	n	%	n	%	
Overall repair attempt							
1st repair	323	79,2	47	11,5	38	9,3	
2nd repair	82	66,7	27	22,0	14	11,4	
3 or more repairs	56	49,1	26	22,8	32	28,1	<0,001
Missing=26							
Etiology type							
Obstructed labor	357	69,1	93	18,0	67	13,0	
Iatrogenic+	84	81,6	6	5,8	13	12,6	0,007
Missing= 51							
Localization of fistula							
VUF, jxtcerv, VVF	285	81,0	33	9,4	34	9,7	
Jxturet, urethral	103	56,6	50	27,5	29	15,9	
Circumferential	17	34,0	19	38,0	14	28,0	<0,001
Missing=87							
Size of fistula							
<=2 cm	302	72,4	66	15,8	49	11,8	
>2-4 cm	97	69,3	23	16,4	20	14,3	
>4 cm	22	47,8	10	21,7	14	30,4	0,005
Missing=68							
Amount of fibrosis							
Without fibrosis	224	87,2	18	7,0	15	5,8	
Slight to moderate fibrosis	201	67,7	59	19,9	37	12,5	
Severe to vaginal stenosis	33	37,9	24	27,6	30	34,5	<0,001
Missing=30							
Distance to fistula							
>4 cm	118	83,7	9	6,4	14	9,9	
<=4 cm	300	65,2	92	20,0	68	14,8	<0,001
Missing=70							
Duration of fistula							
0- <6 months	106	80,3	16	12,1	10	7,6	
6-12 months	70	75,3	13	14,0	10	10,8	
> 12 months	255	66,6	68	17,8	60	15,7	0,033
Missing=63							
Overall outcome all operations	475	71,4	104	15,6	86	12,9	
Missing=6							

n=671 operations, + TGF fistula is grouped with the iatrogenic fistulas
VUF= Vesicouterine Jxtcerv=juxtacervical Jxturet=juxtaurethral

Previous repairs As much as 179 of the patients (31%) had undergone previous repairs before treated at Panzi hospital. The majority of these, 58%, had one previous attempt, while 23% had two previous attempts and the remaining 19% had three or more previous

attempts. The failure rate of surgery increased for each operation being 9% (38/408) for the first operation, 11% at the second and 28% at three or more operations (p<0,001).

Etiology type It appears that etiology type is a factor associated with outcome. Of the iatrogenic fistulas, 82% were cured and nearly 6% were incontinent after surgery, while only 69% of those caused by obstructed labor were completely cured and 18% remained incontinent after the repair. The difference was significant (p=0,007).

Localization Fistulas located high up -midvaginal, juxtacervical or vesicouterine (VUF)- had the best outcome, with 81% (285/352) being completely cured and 9% (33) remaining incontinent after surgery. Of those located at the urethral or near the urethral area, only 57% were completely cured and as many as 28% remained incontinent after the surgery. Circumferential fistulas had the worst outcome, with only 34% (17/50) being completely cured and as many as 38% still being incontinent after the surgery. It is evident that the localization of fistula was significantly associated with outcome (p <0,001).

Distance The distance between the external opening of the urethra and the border of the fistula was associated with outcome. Fistulas located more than 4 cm up, i.e. fistulas situated proximal to the bladder sphincter, the success rate was 84% (118/141) with 6% (9/141) remaining incontinent. For those with a distance less than or equal to 4 cm, the success rate was 65% (300/460) with 20% remaining incontinent (p<0,001).

Route of repair Only 3% of the fistulas caused by obstructed labor were repaired abdominally as compared to 50% of fistulas with an iatrogenic origin. Success rate for fistula closure was 97% for those repaired abdominally and 88% for those repaired vaginally (p=0,006 Fisher's Exact test). No patients remained incontinent after being repaired abdominally, while as many as 16% of the women repaired vaginally remained incontinent (p<0,001, Fisher's Exact test).

Size 69% of the fistulas (421/608) were less or equal to 2 cm in size. The size of fistula was a significant factor of outcome (p=0,005, Chi-square test). The small fistulas, 0-2 cm in dimension, had a success rate of 72% (302/417) while those greater than 2 but less than 4

cm had a slightly lower success rate, at 69% (97/140). The success rate dropped considerably for those greater than 4 cm, down to 48%. The same trend was seen for the outcome of continence. For fistulas up to 2 cm, the rate of incontinence was 16%, also 16% for those between 2 and 4 cm, and 22% for those over 4 cm in size (p=0,005).

Fibrosis Amount of fibrosis was strongly associated with the outcome of surgery. For fistulas without fibrosis, as many as 87% (224/257) were completely cured. The outcome dropped to 68% for those with slight to moderate fibrosis and to 38% for those with severe fibrosis or vaginal stenosis (p<0,001). The analysis also revealed that the rate of incontinence increased with the amount of fibrosis, from 7% to 20% and up to 28% using the same categories respectively.

Duration The delay of receiving fistula treatment was more than 12 months for the majority (63%) of the patients. The duration of the fistula was slightly associated with the outcome of surgical repair (p=0,033). Success rate was highest for patients treated within 6 months after the development of fistula, with a success rate of 80% (106/132). For those that came for treatment between 6 to 12 months of fistula development, the success rate dropped to 75% and for those that came after 12 months, the success rate decreased further to 67%. Incontinence increased from 12% to 14% to 18% for the same variables respectively. The regression analysis, however, did not confirm that treatment delay had an independent influence on outcome (table 9 and 10).

Surgeon's experience We also analyzed whether the experience of the surgeon influenced outcome of surgery (with no regards to the characteristics of the fistula). Panzi hospital being a training centre for fistula repair in eastern DRC, admits four doctors each year in a training program to learn fistula repair. We grouped the fistula surgeons into three categories; junior-, senior- and guest surgeon. The doctors in the training program were classified as juniors, the two experienced fistula surgeons, Dr. Mukwege and Dr Nessy were classified as seniors and all visiting doctors were coded as guest surgeons. In the period studied, the vast majority of the operations were performed by one of the two senior surgeons at Panzi, 67% (448/671). The overall success rate of operations performed by the senior MDs was 68% completely cured, 16% failures and 17% incontinence. Of the 168

operations (25%) performed by the junior surgeons, the overall success rate were 83%, 5% failure and 13% incontinence. Guest MDs performed 55 operations in the period with an overall success rate of 69%, 15% failure and 16% incontinence. Most likely the more difficult repairs were done by the senior doctors and guest doctors, thus a lower success rate.

Prognostication At time of surgery the surgeon indicated the prognosis for surgery outcome. Comparing this expected prognosis with the actual outcome provided us with information on the accuracy of the surgeons' assessment. The analysis signified that the assessment made was quite on target as women assessed to have an excellent prognosis had a success rate of 90% completely cured, women with a good prognosis were 84% completely cured, women with a medium prognosis were 51% cured and women with a weak prognosis only 23% were cured.

4.3 Predictors of surgery outcome

Predictors of unsuccessful fistula closure are illustrated in table 9 and predictors of outcome for incontinence are demonstrated in table 10.

Table 9 - Predictors of unsuccessful closure of fistula

			Unadjusted (crude)			Adjusted (multivariate)		
				95% CI			95% CI	
Predictors	**n**	**%**	**OR**	**lower**	**upper**	**OR**	**lower**	**upper**
Amount of fibrosis								
Without fibrosis	15	5,8	1,000			1,000		
Slight to moderate	37	12,5	2,296	1,229	4,289	1,615	0,753	3,467
Severe or vag stenosis	30	34,5	8,491	4,286	16,822	4,429	1,884	10,413
Overall repair attempt								
1st repair	38	9,3	1,000			1,000		
2nd repair	14	11,4	1,251	0,654	2,393	1,609	0,726	3,567
3 or more repairs	32	28,1	3,800	2,242	6,440	4,662	2,175	9,993
Distance to fistula								
> 4 cm	14	9,9	1,000			1,000		
<=4 cm	68	14,8	0,635	0,346	1,168	0,249	0,121	0,509
Size of fistula								
<=2 cm	49	11,8	1,000			1,000		
3-4 cm	20	14,3	1,252	0,715	2,190	1,285	0,632	2,615
>4 cm	14	30,4	3,286	1,64	6,585	3,471	1,356	8,884
Place of fistula								
VUF,jxtcerv, VVF	34	9,7	1,000			1,000		
jxturet,urethral	29	15,9	1,773	1,042	3,017	1,106	0,559	2,186
circumferential	14	28,0	3,637	1,786	7,409	2,233	0,871	5,729
Duration of fistula								
0-<6 month	10	7,6	1,000			1,000		
6-12 months	10	10,8	0,441	0,219	0,890	1,038	0,347	3,103
> 12 months	60	15,7	0,649	0,318	1,321	1,016	0,402	2,565
Age at fistula repair								
<20 yrs	6	8,5	1,000					
20-34 yrs	38	11,9	1,173	0,636	2,165	Not brought into multivariate analysis		
>34 yrs	23	11,1	1,287	0,561	2,956			

Table 10 – Predictors of incontinence

			Unadjusted (crude)			Adjusted (multivariate)		
				95% CI			95% CI	
Predictors	**n**	**%**	**OR**	**lower**	**upper**	**OR**	**lower**	**upper**
Amount of fibrosis								
Without fibrosis	18	7,0	1,000			1,000		
Slight to moderate	59	19,9	3,653	2,084	6,402	2,548	1,304	4,980
Severe or vag stenosis	24	27,6	9,051	4,444	18,447	4,929	2,083	11,664
Overall repair attempt								
1st repair	47	11,5	1,000			1,000		
2nd repair	27	22,0	2,263	1,330	3,851	1,254	0,624	2,520
3 or more repairs	26	22,8	3,191	1,829	5,568	2,796	1,319	5,926
Distance to fistula								
> 4 cm	9	6,4	1,000			1,000		
<=4 cm	92	20,0	0,249	0,121	0,509	2,166	0,899	5,220
Size of fistula								
<=2 cm	66	15,8	1,000			1,000		
3-4 cm	23	16,4	1,085	0,641	1,837	0,725	0,367	1,435
>4 cm	10	21,7	2,080	0,941	4,599	1,928	0,683	5,444
Place of fistula								
VUF,jxtcerv, VVF	33	9,4	1,000			1,000		
jxturet,urethral	50	27,5	4,192	2,558	6,871	2,435	1,321	4,491
circumferential	19	38,0	9,652	4,573	20,373	6,372	2,475	16,402
Duration of fistula								
0-<6 month	16	12,1	1,000			1,000		
6-12 months	13	14,0	0,566	0,314	1,021	1,080	0,409	2,853
> 12 months	68	17,8	0,696	0,364	1,333	1,008	0,453	2,246
Age at fistula repair								
<20 yrs	17	23,9	1,000					
20-34 yrs	46	14,5	0,667	0,403	1,102	Not brought into multivariate test		
>34 yrs	24	11,6	0,156	0,046	0,529			

Fibrosis The adjusted analysis demonstrated that amount of fibrosis was significantly associated with unsuccessful fistula closure. The patients with severe fibrosis or vaginal stenosis had a 4,4 (CI 1,9-10,4) higher chance of unsuccessful fistula closure and 4,9 times higher chance of incontinence compared to those without fibrosis (CI 2,0-11,7).

Previous repairs The overall number of repairs was significant factors for unsuccessful fistula closure. Patients repaired three or more than three times had a 4,6 (CI 2,2-9,9) times higher chance of unsuccessful closure as compared to those with no previous repair and a 2,7 times higher chance of incontinence (CI 1,3-5,9).

Distance to fistula The distance between the external urethra and the border of the fistula were not significant for fistula closure or continence when adjusted for other variables. It was almost significant for continence with an odds ratio (OR) of 2,1 (CI 0,899-5,22).

The dimension/size of the fistula was a significant factor for non-closure of fistula when adjusted for other factors. The largest fistulas, those greater than 4 cm, had an OR for non-closure of 3,4 (CI 1,4-8,9). The size of fistula was not a significant predictor for incontinence.

The place of fistula was a strong predictor for unsuccessful closure in the univariate analysis. However, when adjusted for other factors, the location was no longer significant. Yet, in the multivariate analysis it was a strongly significant predictor of incontinence. Women with fistulas located at the urethral or near urethral area had a 2,4 (CI 1,3-4,5) higher chance of remaining incontinent after surgery and women with circumferential fistulas had 6,4 (CI 2,5-16,4) times higher chance of incontinence .

Duration of fistula was neither a significant factor for the outcome of closure nor for continence when adjusted for other variables.

Age at fistula repair was not a significant factor for fistula closure in the univariate analysis and was not brought into the multivariate analysis.

4.3.1 Fistulas caused by obstructed labor

In the above section, the regression analysis included both fistulas caused by obstructed labor and those of iatrogenic causes. Since the iatrogenic fistulas were a quite diverse group of fistulas, we were unsure whether this group disturbed the results of the analysis. Especially since the obstructed labor group were more homogeneous. We did a separate regression analysis on the obstructed labor group to assess whether factors influencing outcome were different when analyzing this groups exclusively. All together, there were 522 operations performed on 470 patients in the obstructed labor group.

The adjusted regression analysis for the obstructed labor group found similar predictors influencing unsuccessful closure and incontinence as in the previous section. Amount of fibrosis was a stronger factor for unsuccessful fistula closure with OR of 5,7 (CI: 2,1-15) as opposed to 4,4 (CI: 1,9-10,4) for the patients with severe fibrosis or vaginal stenosis. Similarly, fibrosis was a stronger factor for incontinence with an OR of 5,7 as oppose to 4,9. Otherwise, overall repairs, dimension/size of fistula and localization of fistula were similar predictors of outcome in the obstructed labor group as found above with similar ORs. Equally to the analysis above, distance and duration were not significant factors.

5. Discussion

5.1 Summary of important findings

The main research objective of the study was to establish knowledge of the characteristics of gynecological fistulas in the eastern DRC. Special attention was given to fistulas caused by obstructed labor, medical mismanagement (iatrogenic) and fistulas caused by sexual violence. Only a few case reports have been published on gynecological fistulas in the DRC previously.

Obstructed labor (82%) was the main cause of gynecological fistulas. Yet, a substantial number, nearly 17% had iatrogenic causes of which the majority (70%) involved caesarean section. Surprisingly for this conflict area, fistulas caused by sexual violence were few, only 5 cases among 604 fistula patients (0.9%). Altogether 17% women were not living with their husband at the time of treatment. Women suffering from fistula for more than five years had a higher rate of divorce, with as many as 23% not living with their husband.

The median age at fistula development was 23 years and 41% of the patients had delivered only once. The patients with an iatrogenic fistula came earlier for treatment, after a median of one year, while it took three years for women with fistula caused by obstructed labor. The median duration of the index delivery was 2 days, and nearly 90% of the babies were still born. The obstructed labor group had a higher still birth outcome than the iatrogenic group. 42% of the women delivered by cesarean section, and 85% of the cesareans had been performed on dead babies. The major differences in the fistula attributes for the two etiology groups were the location of fistula, amount of fibrosis and outcome of surgery in terms of continence. The iatrogenic fistulas tended to have a better success rate, 82% compared to 69% for the obstructed labor group. Success rates for fistula closure were similar in the two groups with 90% for the iatrogenic fistulas and 89% for those caused by obstructed labor. Fistulas repaired via the abdomen had a success rate of 97% for fistula closure.

Factors significantly associated with successful fistula closure were no or only one previous repair, no or little fibrosis, equal or less than 2 cm in dimension and location high up (vesicouterine, juxtacervical or midvaginal). For complete healing (closed fistula and continent) the most powerful predicting factors were number of previous repairs, amount of fibrosis and fistula location. The large study population made it possible to analyze the odds of healing according to number of previous repair attempts. Three or more previous attempts reduced the odds of successful closure by more than 4,6 times compared to women with no previous repairs. Such odds are reported here for the first time.

5.2 Discussion of results

This study is large in terms of research on gynecological fistulas in Sub-Saharan Africa and represents the first large scale series of gynecological fistula reported from the DRC, an area of conflict and political instability.

5.2.1 Fistula etiology

In some aspects our results confirm existing reports on fistula patients in other Sub-Saharan African countries, yet there are also some identified differences. A major difference is fistula etiology. While 82% of the fistula cases in our study were caused by obstructed labor, most research reports a range of 91 to 97% of fistulas to be caused by obstructed labor (2;14;18;29-31). The fistula patients in our study seemed to have a high proportion of fistulas with an iatrogenic origin (17%), mainly following caesarean section. This has not been found to such a high extent in other reports. There might be several explanations for this finding. One explanation may be dissimilar use of terminology/ classification of fistula etiology. As explained earlier, some fistulas are not clear cut as to etiology. Some cases may be partially due to medical mismanagement and partially due to obstructed labor. In the group of 97 iatrogenic fistulas, 89 related to delivery. In 25 of these – those related to cesarean hysterectomy, symphysiotomy and vaginal manipulations/curettage – it is reasonable to consider obstetric malpractice as the main etiology. Yet, for the 59 cases where the cesarean procedure itself was considered the main factor, we have no formal proof of an iatrogenic cause as there might have been an element of obstruction and pressure ischemia as well.

The allocation to etiology group done by the recording surgeon could be somewhat subjective, because it was based on the history given by the patient and the characteristics of the fistula. Despite this, we have reasons to believe that the DRC has a large number of women with fistulas caused by medical mismanagement. Inadequate training of medical doctors combined with too much self-confidence, lack of surveillance and no laws in place for accreditation of whom to undertake emergency obstetric care and related procedures, may be a plausible explanation for the high incidence of iatrogenic fistulas found in our study. In the 70s and 80s, midwifes were taught to perform vacuum extractions and some also did cesarean sections, while in the latter years such interventions have been reserved for the medical doctors, unfortunately with little training. These types of procedures are not regulated by law in the DRC, but rather it is a trend that medical doctors perform all obstetric interventions and nurses and midwifes have gradually been reduced to caretaking.

Another reason for the high rate of iatrogenic fistulas may be the increasing use of cesarean section in general (32). Health facilities, usually operating on a cost recovery basis, make more money on performing caesarean sections than vaginal deliveries. There are also some reports that donors subsidize cesarean sections and not vaginal deliveries, giving the facilities incentives to perform surgery. Vacuum extraction has become almost forgotten in many places. Experienced midwives educated to perform vacuum deliveries have to a large extent been replaced by inexperienced doctors trying to solve most obstetric problems by performing cesarean section. These interventions are performed to late in labor and under inappropriate conditions. It is alarming that 85% of the cesarean sections were performed on dead babies. Craniotomy or other fetodestructive methods were almost never used.

There are several possible pathophysiological mechanisms by which a fistula could develop after cesarean section. Cesareans done late in labor are technically difficult to perform. Isthmus uteri and the bladder are lifted high up. Bladder damage can lead to vesicouterine fistulas. As the fetal head is difficult to lift up, tear easily appear. Manipulations, bleeding and suturations can worsen the already impaired local circulation. Amnionitis after long-lasting labor of a stillborn baby imply risk of spreading infections. Bladder paralysis postpartum or postoperatively is frequently overlooked and urinary retention not properly drained.

Vesicouterine and ureterovaginal fistula locations are almost always related to a surgical trauma. Previous studies reports that over 80% of fistulas following cesarean section are vesicouterine fistulas (20-22). We found a lower rate, as 29 of the 59 fistulas (49%) following cesarean section were vesicouterine fistulas and 67% were either vesicouterine or ureterovaginal. One explanation for this may be that previous reports are from countries where there are better assisted deliveries while our study includes women that have been in labor for several days. Another explanation may be that some juxtacervical and vesicovaginal fistulas were included in the group considered to be caused by cesarean section. Previous reports have been few patients and may increase uncertainty in conclusion. Our study found 59 fistulas appearing after cesarean section, 22 presented after repeated surgery. The rate of repeated cesarean section as the primary cause of fistula was lower than reported elsewhere (20), yet our study confirmed that previous cesarean sections may be a predisposing factor for the development of fistula.

5.2.2 Patient characteristics and obstetric information

Table 11 summarizes the findings in the Panzi study with findings from research in other countries.

Table 11 – Findings in the Panzi study compared to other reports

	DR Congo	Nigeria			Ethiopia		Niger	Zambia	East Africa
	Sjøveian	Melah et.al	Audu et.al	Wall et.al	Kelly	Muleta	Roenneburg et	Holme et.al	Raassen et.al
Characteristics	n=470 (1)	n=80	n=88	n=899 7	n=309	n=1210 4	n=90	n=239	n=581 1, 4
Median age at fistula dev	22 yrs	19,3 yrs		27 yrs	22,4 yrs	21,6 yrs		22 yrs	22 yrs
Median heigh of patients	150 cm	148,2 cm						148 cm	153 cm
Mean duration of labor in days	2 days	3,6 days		>=2 days	3,9 days				2 days
Median duration of leakage	3 yrs	5,3 yrs					3 yrs		11 months
Materal mortality									
Obstructed labor etiology	80,60 %	93,70 %	85 %	96,50 %	97,00%	96,00%	96,66 %		90,90 %
Surgical trauma etiology	16,80 %	2,50 %	10 %	1,28 %					
VVF	71 %							90,10%	95 %
RVFs	2,10 %	10,00 %		4,00 %	7%			1,45%	2,80 %
RVFs+ VVF	3,10 %				15%			6,56%	2,20 %
Fistula following first pregnancy	46 %	94,00 %	51,30 %	45,80 %	63,00%	55,00%	41 %	49%	45,10 %
Fistula following 4th + pregnancy	27,80 %			20,00 %		25,30%		27,60%	
Still births for index delivery	92 %			91,70 %	93%	93%	55 %	78,10%	
Overall reproductive outcome	38 %			30,00 %			46 %		
Patients living with fistula > 1 yr	66 %	58,80 %					60 %		46,80 %
Case admission <=6 months	20 %						39,90 % 5		
Patients divorced	19 %	73,75 %		71,07 %	>50%	43,80%		15,10%	27,00 %
Patients married at time of repair	61 %			26,40 %				75%	56,80 %
Patients <150 cm	58 % 2	65,00 %		79,40 %					70 % 6
Patients operated for the first time	69 %	93,80 %			92%			72,60%	
Successfull closure	88,80 %			92,00 %		92,60% 4	77 %		93,80 % 4
Incontinence	17 %			16,30 %	6%		22 %	17,30%	17,70 %
Completely cured	71 %		68,10 % 3		88%		57 %	72,90%	

1 Used only the fistulas with obstruced labor etiology
2 <= 150 cm
3 Article does not clearly define successrate. Assuming complete success
4 First time surgery only. Those operated more than once, excluded in report
5 Within one year
6 < 156 cm
7 Obstetric fistula only

Age & Parity The majority (55%) of the women developed fistula in the age between 20 and 34 years old. Age at the onset of fistula seems to be higher in the women in the DRC compared to women in Ethiopia and Nigeria while it seems to be more similar to the age composition in Zambia and East Africa. In Zambia and East Africa, the median age at fistula development is 22, which is the same as the median age (for obstructed labor patients), in our study. While in Ethiopia the majority of the women tend to be young primigravida (3;14;29), the majority of the women in the DRC were multiparous (59%). In two studies in Nigeria about 45-51% were young primigravida (2;33), while in one study as much as 94% of the women developed fistula after their first pregnancy (18). The differences in age and parity at the onset of fistula in the DRC compared to Ethiopia and parts of West Africa may be explained by differences in the practice of early child marriages and the use of harmful traditional practices such as female genital cutting in those countries. Earlier marriages usually mean exposure to pregnancy at an early age when mature pelvic capacity is not yet reached and thus greater risk of obstructed labor. Child marriages are not very common in the DRC, as it is in Ethiopia and in some places in Nigeria, neither is any form of female genital mutilation. In our study, as many as 34% of the women developed fistula after four or more births which gives us a reminder that grand multiparous women also are at risk and must not be forgotten when developing prevention strategies. One explanation that multiparous women may be at risk is increased birth weight with each pregnancy, decreased uterine contractivity coupled with inadequate obstetric care.

We also found in our study that there were differences in the age and parity composition depending on which province the patients originated. While in North Kivu, the patients tended to be young primipara, in South Kivu they tended to be older, however had a higher portion of lower stature women compared to those in North Kivu.

Height Most patients in our study (57%) originated from South Kivu and the major ethnic group in this province, Bashi, is usually short in stature. Information on ethnic group was not indicated in patient records, nevertheless, our results confirmed that the patients tended to be short stature, with a median height of 150 cm. In theory, short women will have small babies (at least if the father is of “regular” height) and the height itself may not be directly related to narrow pelvis and development of fistula. One explanation may be

malnutrition in early years of development leading to stunting and risk for obstructed labor due to cephalopelvic disproportion (16). Malnutrition has been a major problem in the DRC as the eastern part of the country has been plagued with several wars since the nineties up until today. The population has been forced to flee many times, and though he soil is exceptionally fertile, the numerous conflicts have disturbed food security and resulted in widespread poverty and malnutrition. A disturbing 16-20% of children under five suffer from malnutrition and at least 1,3 million children under five are affected by acute malnutrition (34). Adult malnutrition is also a problem and it is reported to be an exclusively feminine phenomenon (35). Some studies claim that malnutrition is a risk factor for fistula (1;14;16), while others claim that this needs to be further researched (3). Heavy workload and burdens on the back of young girls could also influence the development of the pelvis.

Marital status Our study found a lower number of women separated from their partners than what is evident in other literature. Nigerian fistula women seems to be suffering the most, with as much as three quarter of the fistula women not maintaining their marital status (2;18), while in Ethiopia around half the fistula women were divorced (14;29) and about one third of fistula women in a study of fistula patients in East Africa (31). Only one country had a lower divorce rate than in the DRC, and that was a study of fistula patients in Zambia (17). The large proportion of women still married in our study is not easy to explain. It may be related to differences in the acceptance of divorce practices compared to other countries, or it may be that women were too ashamed to admit they were abandoned or divorced. A woman's' identity is much related to her marital status in the DRC. The study did not discriminate between monogamous or polygamous marriages, and it might be that many women had become second wives. Our study revealed that the divorce rate was higher in the obstructed labor group than in the iatrogenic group. One explanation for this may be that the iatrogenic group came to treatment sooner, tended to be older and had on average a higher median parity compared to the obstructed labor group. Thus their marriages may have been more settled and mature. It may also be that when malpractice was evident, the health worker was to be blamed, not the woman.

Outcome of delivery Our findings confirmed that stillbirth was by far the outcome for most of the deliveries causing the fistula, exceeding 90%. We did find that outcome was better for

those women delivering by caesarean section, yet surprisingly, as much as 85% of these were stillbirths. Most likely a substantial number of cesarean sections must have occurred after the fetus died. Nearly three quarters of the patients gave birth in a health facility, however we suspect that in most cases the delivery started at home. Later when complications appeared, the woman was most likely transferred to a health facility. We suspect that the transfer to health facility occurred too late. This is evident with the high number of still-births despite the high number of women that stated they gave birth in a health clinic. Another explanation may be that the women did arrive timely at the health facility, but treatment delay and inadequate skills or lack of necessary equipment resulted in fetal deaths.

We had expected to see a higher proportion of home deliveries in women with previous births compared to those delivering for the first time. However our study could not find that the womens' parity impacted whether the delivery took place at home or in a health facility. Prevention strategies should therefore target women delivering for the first time as well as women with multiple deliveries.

Treatment delay It appears that the delay in seeking treatment was higher for women in our study compared to findings from Ethiopia, East Africa and Zambia. Our women took a median of two years to seek treatment, 3 years for the obstructed labor group and 1 year for the iatrogenic group. One explanation that women with an iatrogenic fistula took less time, may be that they were timely referred to the nearest hospital or to Panzi since the fistula was caused by a health worker. The women in East Africa took on average 11 months (31) to seek treatment. While only 23% of our patients came within 6 months of fistula development, more than 50% of women in Ethiopia came within 6 months (14). Treatment delay in our study seems to be similar to delays reported from Nigeria. There are, however, several studies in which women take years before presenting at a hospital (1). What is disturbing with our findings is that as many as 35% of the women lived with the fistula for more than 5 years before seeking treatment. One reason may be difficulties in travel due to absence of roads, lack of money for transport or insecurities. Another reason may be lack of treatment facilities. Only two facilities, Panzi Hospital and DOCs in Goma, are recognized as fistula treatment centers. An added explanation may be lack of knowledge about available

treatment possibilities or fear of stigmatization due to the linkage that has been drawn between fistula and rape. One way to reduce treatment delay due to immobility may be to periodically send doctors from Panzi or DOCs to remote areas for fistula repair. Repair of uncomplicated fistulas are relatively simple, requires little technical equipment and may be performed in most places where necessary anesthesia and nursing care is available. The DRC health system is subjugated the provincial health authorities. Well coordinated efforts and information sharing may pave the way for this type of mobile team to be efficient as well reducing misery for the women. Other ways to reduce treatment delay may be public awareness initiatives informing about available treatment and subsidization of transport.

Although the registration form had education level as part of the question, this information was missing in most of our patient records. In most studies, fistula patients tend to be illiterate, uneducated and part of a marginalized group in the society. We believe that this is also the case for fistula patients in the DRC since poverty is widespread as a result of years of conflict and unrest. Many women give birth at home, unattended and cannot afford antenatal care or obstetric care. The Congolese health system consists mostly of privately run hospitals, mainly working on a cost-recovery basis. Very few state hospitals function well, and unfortunately, though some consultations are supposed to be free of charge, widespread corruption deter the patients from obtaining services. Therefore, most women in the DRC do not have access to antenatal or obstetric care due to poverty.

5.2.3 Fistula attributes and surgery outcome

Fistula attributes vs. etiology When comparing fistula attributes and etiology, we found that the location of fistula tended to be different in the two groups. The obstructed labor fistulas tended to be situated lower down (near urethra or midvaginal), while the iatrogenic ones were located higher up (juxtacervical or vesicouterine). The location of an obstructed labor fistula depends on where the delivery gets obstructed and which tissues are trapped between the bony pelvis and the fetal head (1). Thus, the fistula may engage any adjacent structures in the pelvis. The iatrogenic fistulas are presumably located more strictly to the site of the trauma and therefore tend to be smaller in size compared to those caused by obstructed labor. Further, iatrogenic fistulas had no evidence of long-lasting ischemia caused

by pressure. The iatrogenic fistulas also tended to have less fibrosis, probably because these patients came faster to treatment, had less inflammation and were cleaner from the beginning.

Surgery outcome for the two fistula groups were quite similar for closure, while for continence the iatrogenic fistulas had better outcome. This is mainly due to differences in fistula attributes, which is discussed in further details below.

Previous repairs We found a disturbing high number of women with previous failed repairs before coming to Panzi. While some studies have about 90% or more women being repaired for the first time (14;18), only 69% of the Panzi women were repaired for the first time. As many as 19 women had four or more repairs. We also found that women from North Kivu and other DRC provinces had a higher proportion of women with previous repairs compared to those from South Kivu. We are not surprised to find a high proportion coming from other DRC provinces as we know that there are very few places having the expertise to repair fistulas. However surprisingly many women from North Kivu had previous failed attempts despite that this province has a fistula hospital in Goma. One explanation may be that these women have been repaired at rural centers in North Kivu and transferred to Panzi after failure. However, we did notice that quite a substantial number of women came from the Keshero health centre located in Goma and some even from DOCs. Another explanation may be that the North Kivu patient had a higher proportion of the fistulas caused by prolonged labor which tend to be more difficult to repair.

Coinciding with other studies, our study demonstrated that the relative risk of a failed outcome increased significantly with each repair, especially after two repairs. The fact that many women admitted at Panzi had previous failed repairs upon admission, confirms the need for lawmaking, sufficient training and certification of doctors performing fistula repair. Considering the enormous lack of gynecologist and trained surgeons in the DRC, one may be tempted to suggest that fistula surgery should be confined to specialized fistula centers only. When this is said, we must point to the fact that also the Panzi Hospital had a tendency to re-operate women. 41 operations at Panzi in the period were performed on women with two or more previous (failed) repairs at Panzi. Eight of these had five attempts. As the

healing outcome diminishes, especially after two repairs, it is questionable whether this is fair to the patient. For each repair, the woman gets her hopes up for a life without leaking, but her chance for healing is small and decreases significantly with each surgery. In a small number of cases, palliative interventions like ureterosigmoid deviation should be considered. For others, maybe it is better to prepare them to accept their condition and teach them how to live with their fistula. The leading fistula clinic in Africa, The Hamlin Fistula Hospital in Addis Ababa, has come to terms that some women cannot be healed. They have established a special village for women living with fistula. Here they live, produce handcrafts, do agriculture and some even go to school; a safe haven for the women whom in many cases are outcasts in the society. In the village they experience fellowship and a sense of belonging and acceptance.

Success rate Although the Panzi hospital had a high number of complicated cases, the success rate seemed to agree with other reports on fistula repair. 71% of the patients at Panzi were completely cured at the time the patient left the hospital and 17% remained incontinent. Other research reports a complete success rate ranging from 68-88% (14;17;33) and incontinence ranging from 16-22% (2;17;30;31). The closure rates seemed slightly lower at Panzi, with 89% compare to some reports in which closure rates are above 90% (2;29;31). There are some limitations in defining the success rate of surgery. The Panzi closure rate of 90,7% for patients with no previous repairs is within the WHO requirement of 85%, and almost within the requirement for continence, with 88,5% compared to the guidelines of 90% (36).

Whether a woman is dry, has residual stress incontinence or is still leaking are measures that do not take into account the complex nature of the injury. There are also challenges related to the follow up of patients and assessing the long term effects of treatment. Although we could not quantify the number of patients with a poor long term outcome, we did note that several patients whom were dry and cured when leaving the hospital, returned with a new fistula after some time or suffered from stress incontinence. Even if we had been able to quantify the number of women returning after successful repairs, we would only have information on those returning to the hospital but nothing about the others. Long-term follow up of women have turned out to be very difficult. The women often travel long

distances and do not have postal addresses or phones. Most patients are never seen again after leaving the hospital. However, if thoroughly planned and adequately resourced, a follow-up study is feasible. This may give the much needed information on the long-term effect of fistula treatment.

Predictors of outcome A detailed literature review of published data by Lewis Wall in 2006, suggest that the main prognostic factors for surgery outcome is degree of scarring, degree of involvement of urethra to the fistula, size of fistula and presence of other injuries (1). Other reports are unable to determine significant factors influencing outcome when adjusted for other variables (31). In our study, adjusted odds ratios demonstrated that amount of fibrosis, multiple repairs and size of fistula were significant factors in terms of successful closure. Especially large fistulas and those surrounded with severe fibrosis or vaginal stenosis (the most severe form of fibrosis) were difficult to close. This is probably because wide excisions and mobilization has to be done. This makes the wound closure more difficult. Fistulas with two or more attempts had also a significantly lower closure rate, probably related to the increasing amount of scarred tissue that had been removed. The location of the fistula was a strong significant factor for failed closure in the unadjusted analysis, however when adjusted for other factors the location was not significant for fistula closure. This demonstrates that surgical access, which depends on the fistula location, is normally not the limiting factor. Duration of fistula was significant for fistula closure before adjusted for other variables, however not significant after adjusting for other factors. This is probably because the other important factors such as amount of fibrosis and fistula size tend to increase with time.

Similarly for continence, the amount of fibrosis and multiple repairs were significant factors for success. Wide excisions and mobilization make the bladder smaller and fibrosis of the residual bladder wall hinders adequate dilatation. The unadjusted analysis revealed that a short distance from the outer urethral opening to the fistula and distal location of fistula were significant factors for the patient being continent upon leaving the hospital. However this was not significant when adjusted for other variables, indicating the other variables were of greater importance. Although not significant, we believe that in these cases, impaired sphincter function probably explains the problem. A circumferential fistula, where

the inner part of the urethra and sphincter is destroyed, is particularly prone to postoperative incontinence.

Route of repair Fistulas repaired from the abdomen had better outcome of surgery. Of the 66 fistulas repaired via the abdomen, 64 (97%) had a successful fistula closure. Of the 34 vesico-uterine fistulas repaired, 26 (76%) were repaired abdominally and all were closed 100%. The other eight vesico-uterine fistulas were closed vaginally and four of the operations (50%) were successful. These findings indicate that the abdominal approach gives best results. Only a prospective randomized trial can give further evidence for this. Some authors have argued that although vesico-uterine fistulas are better accessed from the abdomen, they should be repaired vaginally to save cost (20-22). If surgery outcome proves to be better when approached from the abdomen, the price should not be an issue.

Although fistula incidence rate is difficult to establish, the high number of women seen at Panzi Hospital during the 24 month period indicates that gynecological fistulas may be a great problem in the DRC. Factors like high maternal mortality rates, destroyed health infrastructure and lack of proper emergency obstetric care play an important role here. Combined with a suspected high number of backlog and insecurities that keeps haunting the region, the need for fistula treatment will continue to be great for a long time.

5.2.4 Public health interventions

Public health interventions may reduce the incidence of obstetric fistulas. One important intervention is public awareness. Information should be available at rural health clinics targeting both rural health workers and the women themselves. Other channels of information such as radio emission, television and churches should be considered focusing on informing the public on what causes fistula, who is at risk, importance of antenatal care and where treatment is available. It is also important to address child and adolescent nutrition, which is a prerequisite for proper physical growth and general health. Other ways of reducing the occurrence of fistula is more emphasis on training of midwifes in obstetric care, with special attention on assisting complicated deliveries and recognizing when to refer women to emergency obstetric care (EoC). EoC services should be expanded, made

accessible to the general public and be free of charge. Promoting antenatal care and subsidizing deliveries in hospitals / birth clinics may reduce maltreated delivery complications resulting in fistula. A surveillance system of monitoring hospitals and birth clinics should be put in place and standardized reporting forms should be promoted.

Possible public health interventions that may contribute to reducing incidence of fistulas related to medical mismanagement are training of doctors in surgical techniques and proper assessment on when to perform cesarean section and reinforcing collaboration between midwifes and doctors. Donors should be cautious in subsidizing cesarean sections only, as it may create incentives for health clinics to do unnecessary surgery. A surveillance system should be put in place to monitor the activities. Fistula surgery should be performed by trained fistula doctors and complicated fistulas ought to be referred to qualified fistula clinics. Laws must be put in place to regulate these activities.

Fistula should not be associated with sexual violence as this adds more stigmas to the women.

5.3 Discussion of methodology

The limitation of a cross-sectional study like this is that the evidence of causation is weak. This is because exposure and disease is measured at the same time and it is therefore difficult to infer a clear causality (37). Examples of exposures are patient biological factors, demographics, socioeconomic factors, pregnancy and delivery characteristics, whereas outcome, the disease itself, is the development of a fistula. For illustration, in most studies it is inferred that fistula patients are in general poor, uneducated women. However, is it poverty that leaves the women at risk, being that they are uninformed or unable to pay for medical services or is it the development of fistula that makes the women poor as they are not able to work and in many cases excluded from family and social structures? Prospective studies on fistula patients have proven very difficult and costly.

Another weakness of the study is that it was hospital-based. That is, we have analyzed patient records of women that already have the disease. This has potential biases. For one, only patients that were sick were investigated. In developing countries, and especially in the

war affected DRC, not all people come to the hospital. Examining hospital records excludes patients that do not seek care, and therefore distorts the true picture of the disease. Since maternal deaths may be the outcome of obstructed labor, those women are not part of the study population and we might get a variant of the so-called *healthy worker effect* (38). That is, information about the women who had passed away remains unknown and only those alive have been studied. This is a type of selection bias, a systematic error influencing research participation. On the other hand, investigating those that are already sick, have given us a large number of fistula cases to study. This is especially true since Panzi Hospital is specialized in fistula treatment and receives a large proportion of those patients. Furthermore, there were more cases of fistulas following cesarean section in one year at Panzi than in most studies during the past 10-20 years.

An additional inherent weakness is that the cases studied may not be representative of the fistula population in general. However, some researchers argue that representativeness is not necessary in scientific research, rather a fallacy that has plagued epidemiological studies for years (38). This is because the goal of scientific research is not always to imply a conclusion that applies to a specific population, rather to imply a conceptual theory that is not tied to a population, rather to a disease, and the characteristics of it (38). Since Panzi is the regional referral hospital for fistula cases and rape cases, they do receive a large portion of the fistula patients and women subjected to sexual violence. It is currently only two hospitals in the entire eastern DRC that are recognized as having the proper expertise to treat fistula, the Panzi Hospital and DOCs in Goma. As documented in our study, many patients referred to Panzi have been previously unsuccessfully repaired at other facilities, some as many as five times. And as we have established, each repair reduces the chances of a successful outcome tremendously. Since many such cases have been treated at Panzi, we have been able to estimate the odds of a successful outcome according to number of previously repair attempts. These odds have not been reported elsewhere. Therefore, a strength of our study is the large number of women studied, including previously repaired women making it possible to analyze the impact of multiple repairs on surgery outcome.

The ability to prove causation is generally better in case-control studies than in cross-sectional studies. In case-control studies, cases are selected with the illness, and controls without illness. Despite the advantage of utilizing case-control study design, most

observational studies are cross-sectional. This is probably because they are relatively inexpensive and easy to carry out. The Panzi study did not use case-control, rather a cross-sectional study design. We studied retrospective data recorded on fistula patients some years ago. These same data have not been recorded on non-fistula patients, thus there was no data available to compare groups/individuals that have the disease and those that have not. For future research a case-control design should be considered.

A central concern in epidemiological studies is the issue of confounding. A simple definition of confounding offered by Rothman is *"the confusion, or mixing, of effects"* which implies "*that the effect of the exposure is mixed together with the effect of another variable, leading to a bias" (38).* A classical example is the prevalence of Down syndrome at birth and the relation to birth order. It was first believed that the occurrence of Down syndrome increased with increased birth order. However birth order mixed the effect of birth order with mothers' age, inferring the wrong conclusion. By further analysis, examining both of the variables (maternal age and birth order) simultaneously, one was able to resolve the extent of which variable explained the apparent effect of another (38). It turns out that it was the mothers' age that had the far most influence on the prevalence of Down syndrome (38). The Panzi study has investigated a substantial number of fistula cases, running multiple regression analysis to adjust for potential confounding factors influencing surgery outcome. It is one of very few studies that actually have established important factors influencing outcome by running multivariate analysis.

A potential bias in our study is information bias in which there are potential errors in the information collected. A common type of information bias is called recall bias where a subject is asked for exposure information after the disease has occurred (38). This is the case for most studies on fistula as the women already have the disease when they arrive at the hospital. Experience of traumas such as still-birth or exclusion from family might influence the way patients remember certain events and what type of information they choose to give to the interviewer or examiner. It is therefore important to be sensitive to this and to ensure that interviewers are well trained. Another effect is called the interviewer effect. It is well known that the interviewer may have an effect on the way patients answers the questions. For example the patients might answer based on certain expectations or based on what she

thinks is the best way to answer. This is especially a risk if the interviewer is very different from the interviewee, i.e. a westerner vs. a non-westerner.

For the Panzi study, answers were obtained during regular consultation by the national doctor. This may have less information bias related to interviewer effect, as it is just a regular patient-doctor meeting, however, it may have more potential for recall bias, as we are not aware that the consulting doctor is especially trained in interviewer techniques and how to phrase questions. Another weakness is lack of relevant medical experience by the doctors filling out the forms. Panzi runs a training program for fistula surgery and some forms may have been completed by doctors with very little training in gynecology and fistula treatment. However we believe that this potential weakness is not a large problem since 75% of the fistula patients were consulted and treated by one of the two senior fistula doctors at Panzi (Dr. Mukwege and Dr. Nessy) or guest experts. Besides, the junior doctors are normally being supervised by a senior doctor.

Another information bias is inherent limitations in the questions/answers in the in-take questionnaire. For example, when estimating the amount of fibrosis, the questionnaire has closed ended answers such as *without fibrosis, medium fibrosis, moderate* or *vaginal stenosis*. Without any reference to what is considered medium or moderate, it is up to the assessment made by the surgeon. Now, obviously this has weaknesses, especially if there are several doctors doing filling out the form using their personal rather than objective measurement of scale. On the other hand, more than half of the surgeries during the two year period were performed by the same doctor (Dr. Nessy), reducing this bias in our results.

A weakness in our study is the large number of missing data on height. A little over 300 patients (53%) did not have their height recorded in the journal. We do not suspect this to be a systematic error.

Lack of follow-up information is a weakness in our study. As with many similar studies, there is very little information on what happens to patients after discharge unless they return to the hospital. Lack of roads, postal service and phone coverage makes follow-up studies difficult, especially in the DRC which still experiences insecurities in the aftermath of the war. The question arises as to the state of those patients that do not return to the hospital. Are they still cured? Are they still with their husband and family? We identified some

women in our study that was cured at hospital discharge and came back with a fistula. We do not know the magnitude of such cases or the reasons for fistula recurrence. But it supports the much claimed argument that there is a need for a prospective follow-up study to uncover information on the post-surgery outcome.

6. Conclusion

The most common cause of gynecological fistula in the DRC is related to obstructed labor. The number of fistulas caused by medical mismanagement or complicated fistulas due to previous failed fistula repairs were greater than found in previous reports. This suggests a need for added quality assurance and monitoring of the medical profession related to the performance of cesarean section and fistula repair. Additional training and utilization of midwifes and nurses in obstetric care should be emphasized. Fistulas as a direct result of sexual violence is rare, even in a conflict setting like the DRC. Associating gynecological fistulas with rape should be avoided as this may add stigma to the women.

Age at fistula development was older than found in most other studies indicating poorly assisted deliveries and lack of access to emergency obstetric care to be an underlying problem. The long treatment delay found implies a need for more public awareness on the condition and available treatment. Mobile teams of fistula doctors performing repair in hard to reach areas should be considered to reduce treatment delay as well as medical mismanagement.

Amount of fibrosis, overall repairs, size of fistula and localization of the fistula were found to be significant predictors of outcome. These attributes should be emphasized in prognostication. Fistulas considered complex should be repaired by senior fistula surgeons only and fistulas with a low odds of successful outcome should be considered irreparable.

There is an urgency to bring attention to the great need for improved access to quality maternal health care in the DRC. Proper obstetric care is vital to reduce maternal mortality, maternal morbidity as well as many newborn deaths, yet the international community is far behind in funding programs that aims to promote safe motherhood. More emphasis on promoting and increasing access to antenatal care, emergency obstetric services and training of midwifes will prevent women from developing fistulas. Traditional birth attendants needs to be included in prevention efforts and be trained and encouraged to cooperate better with the formal health system.

The Panzi study fills a gap in knowledge about gynecological fistulas in the DRC, yet there are other unmet research needs. Determinants of subsequent social rehabilitation and research that gives more understanding of obstetric performance of previously repaired patients is needed. Most fistula patients are seen when treated, however very few are followed up unless they return to the hospital. A prospective study of this kind will be costly and time-consuming. Nevertheless it may give the much needed information on the physical and social effects of fistula treatment.

Images from the field

The new fistula ward at Panzi Hospital

The fistula ward can accommodate 100 patients

Women waiting for consultation at Panzi

Dr Mukwege was awarded the UN human rights price 2008 for his dedication to Congolese womens' health

Dr John Kelly teaches fistula surgery to Panzi doctors

Team from Addis Ababa Fistula Hospital teaches patient care to Panzi health personnel

It was a puzzle to gather all the data. Some days it was a struggle to stay sane. Sjøveian (left) and Onsrud (right).

One of the youngest fistula patient at Panzi. A four year old girl developed fistula after rape.

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Annex 1 Patient registration form

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VSV PROJECT – VICTIMS OF SEXUAL VIOLENCE

FICHE DE RENSEIGNEMENTS A L'ADMISSION D'UNE PATIENTE SOUFFRANT DE FISTULE UROGENITALE

Noms :
Age :
Age de mariage :
Age au premier accouchement :
Formule obstétricale :
Statut marital actuel :

- o célibataire
- o mariée
- o divorcée
- o veuve
- o séparation
- o Niveau d'instruction

Poids :
Taille
TA
Pouls

Province
Territoire
Village
Tribu
Religion

Référence :
-oui
-non
Référée par……

Estimation de la distance avec la maternité la plus proche :
½ jours
½-1 jour
1-2 jours
>2 jours

CPN :
-oui
-non

Durée des troubles urinaires ou fécales (en jours, sem, ou mois) :

Nbre de réparation antérieur :
Lieux :

Cause de la fistule :
-accouchement
-coit
-chirurgie
-corps étranger
-radiation
-autre cause :

Durée du travail :
-1jour
-2jours
-3jours
-4jours
>5jours

Lieu de l'accouchement :
-à domicile
-à l'hôpital
-au C.S
-au dispensaire
-autre

Mode d'accouchement :
-vaginal
-vaginal+ventouse
-césarienne
-zarate

Complications de l' Accouchement :
-déchirure du périnée
-péritonite
-foot drop (nerveuse)
-hystérectomie pour rupture utérine ;
-contracture musculaire
-aménorrhée

Etat du fœtus :
-né vivant
-mort-né
-mort avant 48h
-jumeaux morts
-jumeaux, un vivant

Maladies associées (IST)
-VIH +
-RPR +
-chlamydia se
-trichomonase
-autres IST

SCHEMA DE LA FISTULE

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INFORMATIONS OPERATOIRES POUR MALADES DE F.U.G.

1. Chirurgiens :

2. Anesthésiste :

3 .Type d'anesthésie :
- spinal
- spinal+sédatif
- spinal+générale
- générale

4. Voie d'abord :
- vaginale
- abdominale
- combinée

5. Type de réparation :
- fistule urinaire
- fistule rectale
- les deux
- incontinence urinaire
- déchirure du périnée
- fistule urinaire et/ou rectale+ Déchirure du périnée.
- dérivation
- autre

6. Nombre de fistules :
- 1
- 2
- 3
- > 3

7. Type de fistule :
- vésico-vaginale
- vésico-urétrovaginale
- urétro-vaginale
- vésico-utérine
- rectovaginale
- urétéro-vaginale
- VVF et RVF
- autre

9. Longueur méat fistule :
- 1 cm
- 2 cm
- 3 cm
- 4 cm
- 5 cm ou plus

10 .Dimension de la fistule:
- 1 cm
- 2 cm
- 3 cm
- 4 cm
- 5 cm ou plus.

11 .Etat des muqueuses :
- pas de fibrose
- moyen
- modérée
- sévère
- sténose vaginale

12. Capacité vésicale :
- pas de vessie
- petite vessie
- moyenne
- capacité normale

13 .Statut du col vésical :
- intact
- partiellement endommagé
- complètement détruit
- aucune information

14 .Statut de l'urètre :
- Intact
- partiellement détruit
- complètement détruit
- pas d'informations

15. Statut des uretères
- tous dans la vessie
- tous en dehors de la vessie
- un seul en dehors

8. Siège de la fistule urinaire :
- urétal
- absence de l'urètre
- déchirure de l'urètre
- juxta urétrale
- médiane
- juxta cervicale
- vésicocervicale
- circonférentielle

16 .Cathétérisme urétéral
- les deux
- un seul
- aucun

17. Classification :
- Van Kees W :
- Goys :

23. Statut du sphincter anal :
- Intact
- Détruit
- Lâche

18. Fermeture de la vessie :
- En un plan
- En deux plans
- Plus de deux

24. Fermeture FRV
- Un plan
- Deux plans
- Plus de deux

19. Graft :
- Oui
- Non

25. Durée de l'intervention
- < à 1 heure
- 1 à 2 heures
- 2 à 3 heures
- > à 3 heures

20. Flap :
- Périnéal
- Labial
- Aucun

26. Complications per-opératoires
- Lésion iatrogène (à préciser)
- Hémorragie
- Choc
- Mort subite
- Autres
- Aucune

21. FRV, longueur entre l'anus et la fistule :
- 1 cm
- 2 cm
- 3 cm
- 4 cm
- ≥ 5 cm

27. Pronostic
- Péjoratif
- Moyen
- Bon
- Excellent

22. Dimension FRV :
- 1 cm
- 2 cm
- 3 cm
- 4 cm
- ≥ 5 cm

28. Autres interventions adjuvantes
- LTB
- Hystérectomie
- Cure de cystocèle
- Cure de rectocèle
- Périnéorraphie
- Autres

INFORMATIONS EN POSTOPERATOIRES POUR MALADES DE F.U.G.

N° code Malade : .....

1. Traitement reçu :
- Transfusion
- Fefol
- Fer
- Antibiotique
- Antipaludéen
- Autre

2. complications post-op :
- Infection pulmonaire
- Infection urinaire
- Embolie pulmonaire
- Hémorragie
- Septicémie
- Infection de la plaie
- Autres

3. Durée du sondage vésical :
- < à 10 jours
- 10 à 14 jours
- 15 à 21 jours
- 22 à 28 jours

4. durée du cathétérisme urétéral :
- < à 5 jours
- 5 à 7 jours
- 8 à 10 jours
- > à 10 jours

5. Issue de la réparation :
- Réussite
- Echec

6. La fistule est guérie mais la malade est mouillée, quelle est la cause de l'incontinence ?
- stress incontinence
- over flow (regorgement)
- petite capacité vésicale
- lésion urétrale

7. Séjour (en jours) :
- pré-op
- post- op
- total

8. Statut à la sortie :
- Guérie
- Améliorée
- Traitement palliatif
- Non guérie

9. Rendez-vous:

10 .Recommandations :

11. Médecin traitant :

Annex 2 Ethical clearance letter from REK Norway

UNIVERSITETET I OSLO
DET MEDISINSKE FAKULTET

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0677 Oslo

Regional Committee for Medical Research Ethics
Southern Norway, Section A
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Date: 1 November 2007
Your ref.:
Our ref.: S-07409a

S-07409a Female genital fistulae in East-Congo. A retrospective study of patients treated at Panzi Hospital in the period 2005-2007. [2.2007.2441]
Project manager: MD, PhD, Prof. Mathias Onsrud, Women's Clinic, Ullevål university hospital.
M. Phil. Student Solveig Sjøveian.
Sponsor: University of Oslo.

Application received on the 28th of September 2007 with the following attachment: Protocol; registration form, variable list (variables that are included in the Panzi Hospital questionnaire, translated from French).

The committee processed the application at its meeting on Wednesday the 24th of October 2007. The project is evaluated according to the Act on ethics and integrity in research of the 30th of June 2006, cf. Ministry of Education and Research's directive of the 8th of June 2007 and the guidelines of the 27th of June 2007 for the regional committees for medical and healthcare research ethics.

The objective of the study is to describe and document various circumstances associated with female genital fistulae in East-Congo, and to evaluate the usefulness of a registration form. Current patient journals and registration forms for the years 2005, 2006, and 2007 should be reviewed. The aim is to include approximately 800 patients in the study. The variables are entered into Excel/SPSS and are analysed and stratified according to the cause of various demographic and clinical characteristics with regard to the results of the treatment. The goal is to obtain data that would be useful for improving measures that prevent fistulae and that can contribute to improved treatment of the condition.

This study does not propose to collect consent for access to the journal data. It could be very complicated in the current context to carry this out and it could also raise further ethical issues. The committee is sympathetic to the grounds for the approach that has been selected here. In this regard, the value of the study is considered to offset the disadvantage of deviating from the key principle of obtaining consent for the use of the journal data (personally sensitive information) for research.

As the committee understands the situation data will be registered de-identified (the direct identifying information removed), instead of being registered anonymised as indicated under item 10 in the application form. However, data will be made anonymous later, i.e. coding will be used only until data is quality ensured.

Decision:
The committee grants its approval that the project can be performed in accordance with the description outlined in the application form.

Yours Sincerely

Kristian Hagestad
Chief County Medical Officer, Spec. of Public Health
Chairperson

Jørgen Hardang
Secretary

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